World Health Organization

COVID-19

Virtual Press conference

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SI	Simon
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JO	John

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FC Hello, everybody. This is Fadela Chaib speaking to you from the Geneva WHO headquarters and welcoming you to our global COVID-19 press conference, a joint one today with GAVI alliance and CEPI, the Coalition for Epidemic Preparedness Innovation today, September 21st.

Before we start I would like to explain why we are not wearing masks. We have set up this room so that we are all physically distancing in accordance with WHO guidance. The room is a large one with a limited number of people in it.

This being said, the subject today is a COVID-19 update with a focus on equitable access to future vaccines, therapeutics and diagnostics so please get your questions ready on this important and interesting subject. As always Dr Tedros, our Director-General, will address you first and joining Dr Tedros to answer your questions we have several WHO experts; Dr Mike Ryan, Dr Maria Van Kerkhove, Dr Mariangela Simao, Dr Soumya Swaminathan, Dr Bruce Aylward and Dr Kate O'Brien.

Joining us remotely are the two principals from GAVI and CEPI, Dr Seth Berkley and Dr Richard Hatchett. The briefing is being translated simultaneously into the six official UN languages plus Portuguese and Hindi; exceptionally today, no Chinese translation. We are sorry for that.

00:02:17

Now without further ado I will hand over to Dr Tedros. Dr Tedros, you have the floor.

TAG Shukran jazeelan, Fadela. What Fadela said is true and when necessary we use masks and it's always in our pocket or bag; on the right side the mask, on the left the sanitiser so we have to always be very, very careful and then of course the distancing too.

Good morning, good afternoon and good evening. Today marks the 75th anniversary celebrations of the founding of the United Nations. 75 years ago the nations of the world came together in the aftermath of the Second World War to resolve that the only alternative to the horrors of international conflict was international co-operation.

Perhaps no crisis since the Second World War has demonstrated more clearly why we need the UN than the COVID-19 pandemic. We can only confront this common threat with a common approach. WHO is proud to be part of the UN family.

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As the nations of the world meet virtually for the UN General Assembly this week WHO has three key messages. First the pandemic must motivate us to redouble our efforts to achieve the sustainable development goals, not become an excuse for missing them.

Second we must prepare for the next pandemic now and third, we must move heaven and earth to ensure equitable access to diagnostics, therapeutics and vaccines. We continue to call on all countries to use every tool at their disposal to suppress transmission and save lives until and after we have a vaccine.

From the beginning of this crisis WHO has championed and supported the global effort to develop a vaccine. We have developed target product profiles, criteria for the prioritisation of vaccines and a core vaccine trial protocol. We have engaged with vaccine developers and academics to standardise lab assays, animal models and other normative methodologies.

We're also helping to match manufacturers with trials, trial sites. In April WHO, the European Commission and many partners established the Access to COVID-19 Tools Accelerator to speed up the development and manufacturing of vaccines, diagnostics and therapeutics and to ensure fair and equitable access for all countries.

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Together with GAVI and the Coalition for Epidemic Preparedness Innovation, CEPI, we also established the COVAX facility which will give participating countries access to the world's largest and most diverse portfolio of vaccine candidates.

The overarching goal of the COVAX facility is to ensure that all countries have access to vaccines at the same time and that priority is given to those most at risk including health workers, older people and others at the highest risk.

We have no guarantee that any single vaccine now in development would work. The more candidates we test the higher the chance we will have a safe and efficacious vaccine. Almost 200 vaccines for COVID-19 are currently in clinical and preclinical testing. The history of vaccine development tells us that some will fail and some will succeed.

The COVAX facility enables governments to spread the risk of vaccine development and ensure their populations can have early access to effective vaccines. Even more importantly the

COVAX facility is the mechanism that will enable a globally co-ordinated roll-out for the greatest possible impact.

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The COVAX facility will help to bring the pandemic under control, save lives, accelerate the economic recovery and ensure that the race for vaccines is a collaboration, not a contest. This is not charity. It's in every country's best interests. We sink or we swim together.

The fastest route to ending the pandemic and accelerating the global economic recovery is to ensure some people are vaccinated in all countries, not all people in some countries. Recent opinion polls show the overwhelming majority of people support equitable access to vaccines.

Our aim is to have two billion doses of vaccine available by the end of 2021. We're encouraged to see large numbers of countries signing up to the COVAX facility but we face some daunting challenges. For the ACT Accelerator to work as planned it must be funded. So far US$3 billion has been invested. This has resulted in a very successful start-up phase but it's only a tenth of the remaining $35 billion needed for scale-up and impact.

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$15 billion is needed immediately to maintain momentum and stay on track for our ambitious timelines. Our challenge now is to take the tremendous promise of the ACT Accelerator and COVAX to scale. We are at a critical point and we need a significant increase in countries' political and financial commitment.

This isn't just the right thing to do; it's the smart thing to do. Our estimates suggest that once an effective vaccine has been distributed and international travel and trade is fully restored the economic gains will far outweigh the $38 million investment required for the ACT Accelerator.

It's now my great pleasure to welcome my friend, Dr Seth Berkley, the Chief Executive Officer of GAVI. Seth, you have the floor.

SB Thank you, Dr Tedros, for that powerful opening statement and for inviting us to join you here today. I'd like to commend the WHO as well as our COVAX co-lead, CEPI, for being such constructive, diligent partners in the effort.

This is a significant day indeed. At a time when societies and economies are under the severest strain we've seen

governments from every continent of the world choose to participate in a plan that secures access to life-saving COVID-19 vaccines not only for their own population but helps protect others as well.

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As of today 64 higher-income countries including 29 economies operating as Team Europe have submitted legally binding commitments to join the COVAX facility. We expect as many as 38 more countries to join in the coming days, many of whom have already publicly stated their intent to do so.

This is critically important as it means that when the funds are deposited we can begin the process of signing formal agreements with vaccine manufacturers and developers which are partners in the COVAX effort to secure the doses needed to end the acute phase of the pandemic by the end of 2021.

I want to acknowledge our vaccine partners particularly who were given the number one spot in Fortune's Change The World list just out today. It means that the COVAX facility is now open for business. These countries plus those that will join in the coming days will participate in the facility alongside 92 lower-income countries that will be supported in the procurement of doses.

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That means that more than 156 economies representing at least two-thirds of the world's population will be working together to ensure global access to COVID-19 vaccines through the COVAX facility.

From today we potentially have a truly global solution to a global problem. This is unprecedented. In the last pandemic a decade ago we saw what could happen without a mechanism like this in place. As swine flu spread across the globe a handful of wealthier countries made deals that bought out the entire global supply of vaccine in development leaving none for the rest of the world.

Working together to ensure vaccines are distributed fairly and equally worldwide is not just the right thing to do, as Dr Tedros said, but it's a far better route out of the acute phase of this pandemic. By signing up countries and not just reserving vaccines for their own populations they're helping to ensure their neighbours are protected, reducing the chance of the disease jumping the border.

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They're hoping to ensure their trading partners are protected, boosting their own damaged economies and ultimately helping to ensure the world is protected, giving us all a better chance of defeating this virus.

With the COVAX facility now open for business our work is just beginning. In the coming days we'll be working with governments that have yet to submit their commitment agreements. These are complex legal agreements so certain economies have requested a little bit of additional time to submit. We'll continue to work with them on that.

We will then move into the next phase of COVAX. The commitment agreements we're announcing today unlock the vital funding and security of demand needed to scale up manufacturing and ensure doses are ready once a safe and effective vaccine becomes available.

We will now begin to work on signing formal agreements with vaccine manufacturers and developers to secure these doses. They have been committed partners in the COVAX facility and we look forward to working with them in the next phase and we will continue to raise funds so that we can ensure that once doses are available for lower-income countries they have the financial support they need to purchase them.

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The COVAX AMC, which is a financing instrument to support the participation of lower and lower-middle-income countries in the COVAX facility has raised more than $700 million against an initial target of $2 billion in seed funding needed by the end of 2020. Reaching this target is vital. For this to be a truly global solution we need to make sure that ability to pay is not a barrier to accessing COVID-19 vaccines.

Lastly and of course with our alliance partners work is already underway to begin to prepare countries for the unprecedented delivery and roll-out of vaccines, which is obviously critical to making them work. Thanks for listening. Back over to you, Dr Tedros.

TAG Thank you. Thank you so much, Seth and that's very, very clear. Now I ask Fadela to proceed with the rest of today's session. Thank you, Fadela.

FC Thank you, Dr Tedros and thank you, Dr Berkley. We will now open the floor to questions. Before that we will ask the CEO

of CEPI, Dr Richard Hatchett, to give us his opening remarks. Dr Hatchett, you have the floor.

00:15:53

RH Thank you very much. I would like to thank first the countries who have formalised their commitments to the COVAX facility. I also want to thank my friends, Dr Tedros and Dr Berkley, for their opening remarks and finally I would like to thank all my colleagues at WHO, at GAVI and CEPI who have worked tirelessly for months to help bring the COVAX facility into existence.

Months ago we foresaw the risk that the scramble for vaccines would result in the same kind of misallocation of vaccine that we observed in the last pandemic in 2009. CEPI as an organisation invested early and in nine vaccines, creating the largest global portfolio of COVID-19 vaccines in the world.

Today is an important milestone on the way to the development of a globally fair allocation. It is the product of the scientific community of rich and poor countries and global NGOs coming together to face a common threat.

CEPI and GAVI and WHO are fully committed to ensuring equitable access to COVID-19 vaccines. COVID-19 cannot be beaten one country at a time. We must be able to share life-saving vaccines globally at the same time.

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Humankind has never done this before with any new life-saving medical technology or intervention. We are on our way to setting a very important precedent for the world. What we are seeing today in the announcement of the countries that have formally committed to join the COVAX facility is hugely encouraging; a genuine global commitment to respond to a pandemic threat through collective action.

There is indeed a very long way still to good. We are not out of the woods. We must continue to invest in critical research and development and to fund that research and development. We must finish the ongoing clinical trials. As Seth said, we must conclude agreements with industry to provide vaccine through the industry and we must help countries prepare to receive vaccine.

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Finally we must have realistic expectations about the efficacy of the vaccine and about the timing of its delivery. Vaccines are a critically important tool in the fight against COVID-19 but they are only part of the world's response and we must support the other parts of that response as well.

Today, I believe, will come to be seen as an important milestone and perhaps what will come to be seen as a turning point in the fight against COVID-19. Thank you and let me turn this back over to Dr Tedros and to our colleagues at the WHO.

TAG Thank you. Thank you so much, Richard. I'm very, very grateful and so unprecedented, the collaboration that we're having between us. I met some member states today and they told me how proud they are of how we're partnering together; GAVI, CEPI, WHO, Global Fund, Unitaid, FIND, the World Bank, the private sector, civil society and others in the ACT Accelerator.

I was really proud to hear about it and I told them the reason why this partnership of different health agencies is succeeding and why we're working very hard and I know - you know it; I don't want to go into details but I wanted to just use this opportunity to appreciate and tell you how honoured WHO is to partner with GAVI, CEPI and the rest of our partners. Fadela, back to you.

00:20:40

FC Thank you, Dr Tedros. Thank you so much, Dr Hatchett. Now that we have heard from the three principals I would like to open the floor to questions from journalists. I remind journalists that you need to use the raise your hand icon in order to get in the queue to ask questions.

We have several journalists online. I will start with Jenny Le Ravello from Genex. Jenny, can you hear me?

JE Hi, Fadela. Can you hear me?

FC Very well. Go ahead please.

JE Okay. Thank you so much for taking my question. Two quick questions; one is on the COVAX AMC facility. Mr Seth Berkley talked about, they will begin to sign agreements with partners in the coming weeks. Last month there was a collaboration between the Gates Foundation and the SII about ensuring up to 100 million doses through the COVAX facility for LMICs. I just want to get an update in terms of, how many more are you expecting in your current negotiations with vaccine partners and from which vaccine manufacturers?

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And just very, very briefly secondly on the ACT Accelerator I just want to get a sense because the original investment case was, I think, around $31 billion and there's now a discussion of a funding gap of 35 billion. Can I just get a clarification of the numbers please? Thank you very much.

FC Thank you, Jenny. Dr Berkley, do you want to take the first question?

SB Yes, absolutely. Until we have signed agreements and finance for the upper-middle-income and high-income countries we cannot go ahead and close those deals. That's why this is such an important day but for the AMC of course we already have an engagement going on that and we have now signed for up to 850 million doses of vaccines as part of the AMC.

The rest of the manufacturers that Dr Hatchett has talked about, both from the CEPI portfolio, vaccines from potentially the Gates portfolio if they make it but also vaccines from the industry that have not yet collaborated on moving forward are all eligible for this so we will be looking during this next period to supplement those agreements that have already been made.

The last thing I want to say about this is that you heard the goal for us is to try to get to two billion doses. Of course that's two billion doses of safe and efficacious vaccines. We know the failure rate for vaccines historically is quite high with four out of five even in clinical trials failing so what this means is we are going to have to cut many more deals to get to the numbers we want.

So that's' where we are right now but obviously we'll be transparent and as more information comes out we'll share it with you.

FC Thank you so much, Dr Berkley. The question on the ACT Accelerator; Dr Bruce Aylward please.

BA Thank you very much, Jenny. The first investment case for the ACT Accelerator that was released on 26th June gave the costs for the three, what we call product pillars so for the vaccine, therapeutics and diagnostics work of the ACT Accelerator which was indeed $31 billion at that time.

But in that investment case we highlighted there's a fourth part of the ACT Accelerator which is vital to its success and that's what we call the health systems connector. That part of the ACT Accelerator is the work to ensure that when these new products hit the countries they can actually be utilised in the most efficient

and effective way possible so that part of the budget has been built in.

So what you're seeing today in the new investment case which will be fully revised and released later this week will include the cost of what we call that health systems connector so the total cost of the three major product pillars plus the health systems connector, the gap is $35 billion as the Director-General referred to.

The urgent need is actually the $15 billion that we need right now to maintain the momentum. As Dr Berkley said, the COVAX facility is now open for business. We have new therapeutics; dexamethasone we've been talking about, that we know reduces mortality. We've got new rapid antigen tests that show great promise so there's great promise right now to get a step change in the global response to COVID-19 but it requires seizing this moment with the $15 billion of financing needed to fully exploit these opportunities.

FC Thank you, Dr Aylward. We will take a question from the next journalist, Antonio Broto. Can I just kindly ask journalists to limit your questions to one because we're very happy to have a large number of journalists but limit your questions to only one please. Antonio from EFI, Spanish news agency. Antonio, you have the floor.

00:26:35

TR Good afternoon and thank you for giving me the floor. On the list we can see above all the fact that the United States is not in there and also we see that China is not in there. Maybe you could let us know if there have been any negotiations with the authorities in China so that they join COVAX or is there a hope in the future that they may become part of the network? Thank you.

FC Thank you, Antonio. Dr Berkley.

SB The purpose of the COVAX facility is to try to work with every country in the world and I can assure you that we have had conversations and will continue to have conversations with all countries. That relates to both whether they join the facility and the advantages of doing that but also for countries that are producing vaccines, if they have successful vaccines that come out, how we can make sure that those are made available to others in the world so we will continue that dialogue.

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FC Thank you, Dr Berkley. Now I would like to give the floor to Helen Branswell from Stat. Helen. Bruce, do you want to add something? No, okay. Helen, you have the floor.

HE Thank you. My question was just asked but I guess I will come up with another. It's hard to gauge how successful this has been. 64% of the world's population are going to be in the programme. Would you have expected more? I'm puzzled that more are not in.

FC Thank you, Helen. Dr Berkley.

SB Thank you, Helen, for that question. Remember, we announced today who has signed up with a legally binding commitment. We have many other countries who have expressed interest to participate and who were because of legal issues or parliamentary issues or others delayed in making those.

So we have 38 other countries that we expect - and maybe all of them won't show up but I expect the numbers will grow significantly larger than they are today but we'll see.

FC Thank you, Dr Berkley. I think Dr Edward has something to add. Aylward.

00:29:25

BA Thank you, Fadela, and thanks for the question, Helen. I think we can look at this two ways and we've got to look at this as a huge success. When we've got 64% of the world's population as a single entity working together that's huge progress.

As Dr Berkley just mentioned, there are many others that are still interested to join so what we've managed to do - a lot of credit here obviously to GAVI, WHO, CEPI who've worked together on this - is to build a coalition at a time when the world has been so worried about countries going bilaterally.

We now have 64% of the world's population and this is growing still so this is huge progress and, I think, provides a fantastic opportunity to achieve that goal of rapidly reducing the risk of severe disease in as many countries as possible so we can get the world health systems safer, get the societies reopened and then get obviously economies working again as rapidly as possible. This is huge progress.

FC Thank you, Dr Aylward. The next question is from Nina Larson, Agence France Press. Nina, can you hear me?

NI Yes, hi, Fadela. Can you hear me?

00:30:57

FC Yes, very well. Go ahead please.

NI Thank you. I'd like to ask a question on another topic. The CDC on Friday shifted its guidelines to say that small particles such as those in aerosols are the most common vector of COVID-19 and not the large droplets encountered at close range as it stated previously.

It seems to me that WHO has said - and I might be wrong - that aerosols occur in certain settings like in operating theatres but has not given any conclusive information about whether the virus spreads through the air in other settings so I was wondering if the WHO is considering shifting the guidelines on this as well and if you agree aerosol spread is one of if not the main vector of this virus and how concerned we should be about sharing indoor spaces like the one you're in right now. Thank you.

FC Thank you, Nina. I think we will go to Dr Mike Ryan to answer this question. Dr Ryan.

MR Hi. Thank you. Yes, we've seen the postings on the CDC website and we're actually in touch with CDC to better understand the changes that have been made. There are parts of the website that appear to retain previous evidence and parts that appear to change so we're just trying to check with our colleagues at CDC the exact nature of the change if any in their advice regarding this.

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Certainly we haven't seen any new evidence and our position on this remains the same and we've always said going back over months and months about the potential for different kinds of routes of transmission and particularly driven by the context, the proximity, the intensity, the duration and the potential for different forms of transmission including small particle transmission and particularly in poorly ventilated spaces and the need for the appropriate precautions.

Maria can speak to that advice but we are obviously... CDC is a very learned and credible institution so when CDC changes anything we always look to them and ask and get the details and we're currently following up and we'll be doing so over the next 24 hours to understand the evidence that potentially drives any change in guidance. Maria.

00:33:27

MK Only briefly to add because Mike has answered really completely, just to say that we haven't changed our position. We do have a scientific brief that is out that describes all of the different modes of transmission that we are constantly looking at.

As you know, from the beginning transmission and severity are two of the main features of any new pathogen that are really critical to better understand and we are always looking at the literature. What really matters is how we protect people and how we ensure that transmission is reduced and suppressed and countries are having great success in doing so.

So our guidance around physical distancing, the use of masks, avoiding enclosed, crowded settings, make sure you have good ventilation, hand hygiene, respiratory etiquette; manage your risk, really know what your potential exposure may be depending on where you live and where you work and we're working with our member states to ensure that they take appropriate steps to reduce transmission.

FC Thank you. The next question is from Simon Ateba, Africa News Today. Simon, can you hear me?

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SI Yes, I can hear you. Thank you.

FC Thank you. Go ahead please.

SI Simon Ateba from Today News Africa in Washington DC. My question is to Dr Berkley of GAVI. You said that 64% of countries have cemented their commitment to the COVAX initiative with a legally binding agreement. I would like to know how many of those countries are from Africa.

Second, once a successful vaccine is eventually approved how do you intend to carry out vaccination in Africa? Will you start with some countries like South Africa, Egypt, Algeria, Ghana and Nigeria where there are most cases or will you do it at the same time?

If you allow me to quickly ask one last question on what Dr Mike Ryan just said about the CDC, the CDC also said that coronavirus can spread further than six feet. Are you also looking at that area? Do you still stand by the recommendation that six feet is enough to prevent the spread of coronavirus? Thank you.

00:35:46

FC Thank you, Simon. I think we will go to Dr Berkley to answer the first question of Simon's. Dr Berkley.

SB Thank you, Simon. There are 48 African countries that are included in the advanced market commitment. There are eight self-financing countries that can join so right now 48 of those countries are part of the facility and will have access.

The purpose of the regional allocation framework is to try to provide vaccines equally to all participants including developed and developing countries and obviously that has to be also joined to how fast vaccines get produced and what allocation or in what quantities they can be transported.

But the idea would be initially to try to get to health workers around the world and that is up to 3% of a population and then to add doses as vaccines. get made so the idea would be to try to make them available to all countries equally.

After 20% of countries are covered the idea would be that the allocation framework would shift slightly and if there were differences in need that would be taken into account. The last thing I'd say is that there is also a plan to put aside doses for humanitarian emergencies and those of course could also be used in the circumstance where there were substantial outbreaks that needed additional doses.

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FC Thank you, Dr Berkley. I think Dr Aylward has something to add.

BA Thank you for the question, Simon. I just realised as you were asking the question it's important for us to clarify one point. You said that 64% of countries had joined and actually the proportion of countries and economies around the world that have joined the COVAX facility is much higher.

Helen, this goes back to the question that you asked but remember, we now have 156 countries and economies working with the facility and potentially another 38 that are in discussion as Dr Berkley mentioned. That makes nearly 80% of the countries and economies around the world that are already working with the COVAX facility and that number may grow higher.

So when you approach it as a proportion of the countries and economies around the world it's a huge proportion and I just thought to be very clear, that group represents nearly 70% of the world's population but as a proportion of the number of countries

and economies it's even higher, which again is extremely important when it comes to that goal of equitable access.

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The more countries and economies we have working together the better the opportunity to get these products rolled out in the right order to the right people at the right time.

FC Thank you, Dr Aylward. I would like to remind journalists to unmute themselves when they want to ask a question. Now I would like to invite the next journalist, Kai Kupferschmidt from Science. Kai, can you hear me?

KA Yes, thanks for taking my question and thanks, Bruce, for setting me up perfectly; the right people, the right order. Obviously there are different ways of trying to distribute the vaccine in a fair way, in a way that has the maximum impact and I just wonder whether you can speak a little bit to...

You've gone for this two-phased approach where the first phase is proportional to the population and in the second phase countries are prioritised depending on threat and vulnerability. Can you just explain a little bit the modelling that goes into that? There are people who suggest that for instance vaccinating younger people who spread the virus more might be more efficient so if you could just explain a little bit what went into that; I assume it's not pure ethics and science but also politics.

00:40:10

FC Thank you, Kai. I think I would like to ask Dr Mariangela Simao to take this question. Dr Simao.

MS Thank you, Kai, for the question. There are several indicators that will be taken into account. We haven't yet developed them fully - I'm talking about the second phase - because it will depend a lot on the type of vaccine that will be approved, what type of population, the immunogeneicity, who does it protect, does it cover young people, does it work well in older people for example.

So at the moment we're working with two aspects; one is stretch and vulnerability. For this different models will be used that include for example mortality, include rates of infection; it could include health system capacity, ICU coverage for example so it will depend a lot on the type of situation we have when we get to phase two.

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At the moment we're working with the uncertainties we have in relationship to the vaccine itself, the one that will prove to be both safe and efficacious.

FC Thank you, Dr Simao. Now I would like to give the floor to Corinne Gretler from Bloomberg. Corinne, can you hear me? Corinne, please unmute yourself.

CO Can you hear me?

FC Yes, very well. You can ask your question. Go ahead, please.

CO Sorry. I may have missed this earlier but I was wondering if you still expect China will be involved with the COVAX programme or is it maybe one of the countries that asked for more time to commit?

FC Dr Swaminathan, can you answer this question please?

SS Yes, I can start and maybe Dr Berkley would like to come in as well. We've been engaged in discussions with China for the last several months because, as you know, they also have a very active vaccine development programme and several of their vaccine candidates are in advanced stages of clinical trial so this is also of interest to us so we're following those very closely.

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We've had very constructive and open discussions with them and they have always been reiterating their commitment to global access if some of their candidates actually prove to be successful I the clinical trials that are going on. So I think the conversations are going on, it's still open and we're hopeful that more countries are going to join. Dr Berkley might like to add something.

FC Dr Berkley, do you want to supplement please?

SB I think Soumya has done a good job answering that. I'd just say that they haven't signed up but they have publicly expressed their interest in engaging with us and so we will continue to have that discussion.

FC Thank you, Dr Berkley. I would like now to give the floor to Jamie Keaton from Associated Press. Jamie, can you hear me?

JA Yes, hi. Thank you. I wanted to talk about the WHO's threshold for approving or giving its stamp of approval to a COVID-19 vaccine and the minimum efficacy rate. Would you possibly approve the use of a vaccine that's less than 50%

effective, as has happened in some other types of vaccines? Thank you so much.

00:44:21

FC Thank you, Jamie. Dr Swaminathan please.

SS Thank you, Jamie. As you know, we put out the target product profiles for an ideal COVID vaccine. This was several months ago and obviously these target product profiles are to help developers and funders to try to have some benchmarks for when they're developing the vaccine.

We have two scenarios, a vaccine that's used mainly as a preventive and also a vaccine that could be used in outbreak settings to rapidly control outbreaks so they're slightly different product profiles.

But essentially what it describes is a vaccine ideally with 70% efficacy and above but certainly 50% would be the point estimate; that's what we would classify as an effective vaccine. It's also important how these endpoints are studied in clinical trials because as you know, around the point estimates you have confidence intervals and so it's also important that the confidence intervals are not too wide.

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In other words if you do a clinical trial with small numbers of people you could still prove a 50% efficacy but you may have confidence intervals that go all the way down to zero, which means that there's a chance that the vaccine actually doesn't have any efficacy or has very poor efficacy.

So we also specify the lower boundary of these confidence intervals, which is 30%. A vaccine that has less than 30% efficacy is probably not going to have a big public health impact because you can see if you have a 30% or lower efficacy and you vaccinate a certain percentage of the population it's going to be difficult to get to those levels of immunity.

The FDA also has guidance on the criteria; we're very well-aligned, the WHO guidance and the FDA guidance are very well-aligned and as clinical trials are proceeding in phase three we're expecting to see some of these data so it's also going to be important to have criteria for emergency use listing and then ultimately for prequalification.

As you know, emergency use listing is a step on the way to prequalification or to full use licensing and is done in... In

pandemics like this one might consider that but again there are minimum criteria also for safety so one is on the efficacy side.

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But on the safety side we would like to see several months of follow-up to assess the adverse reactions, particularly since we have so many platforms that are currently being tried which are first-time platforms like RNA and the DNA vaccines and even the non-replicating viral vectors have not been used at scale and therefore safety considerations are important because here's a vaccine we're going to use on billions of people and so the risk/benefit profile has to be very, very strong. Kate, do you want to add something?

KOB Yes, I think what I'd like to add to that great explanation about how we consider the evidence from trials, it's really important to remember that there's also a policy process and although vaccines or frankly any product may achieve authorisation, licensure, how that vaccine is actually used, in which groups - and certainly will be taken into consideration the magnitude of the efficacy and in which groups that efficacy was demonstrated.

So at WHO we do have the policy process in motion considering the evidence right now and we'll continue to watch very carefully as that evidence accrues. Thank you.

00:48:17

FC Thank you, Dr O'Brien. I would now like to invite Leroy Da Sousa from Mint India for the next question. Leroy, do you hear me?

LE Hi. I can hear you.

FC Please go ahead.

LE My question is specifically with regard to India. India's part of the GAVI, the AMC-eligible countries but has there been any sort of discussion about payments or the total number of doses that are needed?

Also among the four candidate vaccines that are part of the COVAX facility, apart from the Oxford serum vaccine that is there are there any others - what are the others that are there and are any talks going on with Indian manufacturers?

FC Thank you, Leroy. Dr Berkley, do you want to take this question please?

00:49:25

SB Sure. Thanks for the question. India has a very special role to play. It has a whole group of indigenous vaccines that they're working on. There's a powerful science engine going on there and they also have massive manufacturing capability and so when have had a series of conversations on the R&D side with all of the manufacturers and also with the manufacturers on the ability to scale up and produce.

Of course India is GAVI's largest eligible country and so they are part of the AMC but also given the size of India's population we have always had a special strategic relationship with India and so we have had a series of conversations and will continue to work on those conversations on how we would be able to provide vaccines, which we would purchase, which India would purchase and how those would be scaled up appropriately. I don't know if Soumya wants to add anything to this given her engagement also in this work.

SS Yes, thank you, Seth. I just wanted to add that India is also obviously a very good place to do clinical trials for multiple vaccines because of the population that is exposed but also because of capacity that exists and the institutions that are capable of doing randomised clinical trials so we are discussing with the companies as well as with the ICMR and the Ministry of Health on clinical trials for multiple candidate vaccines, both those made in India as well as those that are available outside.

00:51:12

So we hope that there'll be a lot of activity in the coming months both on the R&D side... There are several candidate vaccines. that are advancing, at least seven or eight of them and so we hope to see results coming from those studies. The first few are now in phase one/phase two and in the next couple of months I think we should start seeing the immunogeneicity and the safety data coming in. They're also in conversation with CEPI for partnerships on R&D.

FC Thank you, Dr Swaminathan. Dr Richard Hatchett, do you want to add something on the vaccine issue?

RH Just to say that the Indian manufacturers, as Seth and Soumya have said, are very much participating in the global response, they are supporting the manufacturing of vaccines by international companies as well as developing their own.

00:52:20

They have a terrifically exciting and robust biotechnology community and we have been deeply engaged in discussions with them and look forward to collaborating.

FC Thank you, Dr Hatchett, thank you so much. Now I would like to give the floor to Sara Whitton from Politico. Sara, can you hear me?

SA Yes, thank you for taking my question. The goal as I understand it for COVAX is to secure two billion doses but given that some vaccines would need two doses and some would need one I'm just wondering why that is the unit as opposed to saying, say, we want to vaccinate two billion people.

When we talk about phase one and phase two and that phase one would give each country enough for 20% does that mean 20% would get a full course or 20% of people would get one dose even if it's a two-dose vaccine? Thank you.

FC Thank you, Sara, for this question. I would like to invite Dr Kate O'Brien to respond.

KOB I think it's important to recognise that the two billion dose number is predicated on the idea that it would be a two-dose regimen. We don't know yet which vaccines are going to reach success and licensure so that's the direction we're planning for but that's really only through 2021. The aspiration of course is to go well beyond 20% immunisation and to extend that to all people who would benefit from protection through vaccines.

00:54:09

I think the other important thing to say is that as we envision the scope and breadth of what needs to be done the delivery at scale enterprise to actually get this number of doses in this time frame to people across all countries is an enormous enterprise and countries are preparing for actually deploying vaccine in all the different ways that that preparation needs to happen; on the cold chain, on data monitoring, on readiness of healthcare workers to actually deploy that vaccine.

So we have to really remember that what we're talking about today is really the first phase of what needs to happen and the aspiration is to assure that we are able to secure more vaccine for more people in all countries who need to eventually.

FC Thank you, Dr O'Brien. I would like now to give the floor to Imogen Foulkes from the BBC. Imogen, can you hear me?

IM Yes, I can. Can you hear me?

00:55:19

FC Please go ahead.

IM Could I just come back to the drivers of infection? Because I wasn't quite sure that Nina's question from AFP got answered as clearly as we might like because I think the question was that CDC was suggesting that aerosol is the main driver of transmission. I know you've never ruled anything out but for a long time you were saying that droplets were the primary driver of transmission.

You say your position hasn't changed. Do you still think droplets are the primary driver of transmission then?

FC Thank you, Imogen. Dr Ryan.

MR Yes, no. I think you may find that the advice that's been posted by CDC is actually draft advice that has been, I think, taken down at the moment as we speak because I think it was maybe posted inadvertently so I believe from that perspective, I think we need to see what the final advice from CDC is but that doesn't mean we can't talk about this very important question which is the spread of this disease.

00:56:33

Unquestionably the disease can spread by many different routes and we've seen that and we believe based on the epidemiologic parameters that the primary mode of transmission is through the respiratory or through the direct person-to-person route depending on the size of aerosols.

We believe that symptomatic individuals infect the majority of people at close range through the direct contamination with droplets and then there is always the risk and is the risk of further transmission at longer distances and Simon Ateba asked earlier about this six feet versus three feet.

There is no question that distance is a factor; there is no question that duration is a factor; there's no question that ventilation is a factor; all of these things. The risks decline exponentially as you move further away from another individual. The risks decline depending on ventilation. The risks increase depending on the density of people and that's why it's so difficult to say with absolute...

Simon asked earlier, is six feet better than three feet? Of course it is. Is nine feet better than six feet? Of course it is. The issue here is to find out what is the best balance of measures that

manage most of the risk and then allow us to be able to exist within our society.

00:57:51

It's the same thing when we talk about the period of time for contact tracing. We say 14 days. That does not mean that 100% of people develop disease in 14 days. What it means is the vast majority of people will develop disease in 14 days. We could follow people up for 30 days or 50 days.

The question is the balance of the resources required versus the benefit we gain in terms of disease control. All of these parameters need to be put together so we still, based on the evidence, believe that there is a wide range of transmission modes.

We believe the disease is predominantly or primarily spread through droplet spread and through larger-droplet nuclei but we have always said that smaller-droplet nuclei can spread this disease and that is very context-driven.

People crowded into a small space without adequate ventilation where they're there for a long duration of time; in that situation aerosol-based transmission can occur and it has been demonstrated to occur. The question is what's driving the day-to-day transmission of the disease and we need to stop all sorts of transmission, we need to look at all types of transmission.

00:58:57

That's why we talk about avoiding crowded spaces, that's what we talk about ventilation, that's why we talk about the duration of time we spend in those spaces. So the advice in that sense does not change; it's about knowing the risks, managing the frequency, intensity and duration of time you spend in the company, around other individuals, in crowded space and when you can't physically distance, when you can't fully manage that to be aware of those risks and to ensure that you always have a mask with you so you can wear that mask in situations where you can't distance yourself appropriately from others and to always remember to maintain good hand hygiene.

These are really important issues and I think we have to level with people; there are no absolute risks, there's no situation where this is risky and this is not and where this is bad and this is good. It's about finding the best balance of behaviour, the best balance of risk that allows us to go back to school.

00:59:55

For example - I'm sorry to go on about this but many countries have brought children back to school successfully, it's been very tough. It's not been zero-risk. The risks of transmission still occur. We're balancing those risks to benefit our children's education, to minimise their risk of exposure or bringing the disease home but it's not zero-risk.

Great credit goes to those schools and local school authorities and governments who've managed to do that successfully but I do think as we move forward in this pandemic we've got to become able to accept that there are very few absolutes in this response and we've got to be able to be smart and make smart decisions.

Smart decisions are made based on understanding risk, minimising risk and then being aware of the residual risk and, as best we can, to avoid that. Maria, I think you may have...

FC Thank you, Dr Ryan. We are going to move now to South Africa, to Sophie Mkwena. Sophie, can you hear me?

SO Yes, I can hear you loud and clear. My question is around the issue of making the drug or the vaccine or whatever medicine available to ordinary people. Ordinary people around the world are asking for a moratorium on all COVID-related patents with the intention to ensure that we don't have a situation where companies and individuals are profiting while people don't have access to such important vaccine or medicine or anything that can help them and also to ensure that you classify health as a public good. What is your reaction as a panel?

01:02:02

FC Thank you, Sophie, for this interesting question. Dr Simao.

MS Let me start and maybe colleagues can complement. I think we are very clear, WHO's very clear when we are talking about COVID technologies that work to save lives and to prevent infections as global public goods. It's in this framework that WHO has been working with partners including GAVI and CETI in the vaccines to ensure that there's equitable access to these technologies.

We understand that for specific products like vaccines for this acute period intellectual property barriers are not necessarily the most important barrier. We expect that next year the most important barrier is the capacity to scale up production and to make these products available and we know that some of these

manufacturers will be selling these products at what we call a cost-plus, which is not intending to have profit.

01:03:11

On the other hand we do have products for example for treatment. When you have a product like dexamethasone which has helped to decrease - is proved to decrease mortality in severe patients, which is not patent-protected, is available across the world - it's a very old drug.

But we have expectations that we may have a new therapy and this could be a biotherapeutic which is - as we speak the current ones in the market for other diseases are very costly and are patent-protected and they're hard to be scaled up and to be copied.

So we do expect that for medicines if any of these new biotherapeutics become proved to be safe and efficacious against COVID we may have IP as a barrier and this is why we're also working together with UNITAID and the Wellcome Trust to address this beforehand and this is in case one of these new therapies becomes available in the market.

For example you have the case of monoclonal antibodies which are already complex molecules and they are already used for other indications and they are very expensive so this is an issue that will have to be tackled and we are tackling it together with partners. Thank you.

01:04:46

FC I don't know if Dr Berkley or Dr Hackett would like to respond also.

SB Yes, I'll just add one word to that. If you look at biologics the main issue is not patents; the main issue is know-how and that's because these are basically living organisms or components of living organisms and therefore the whole process is the critical piece.

In my experience of 30 to 40 years working around vaccines I can only think of a handful of cases where a patent was a major issue. That know-how then becomes very important on how we form the partnerships to have companies be able to transfer technology to other companies and that's a lot of what we're trying to do here, to make that available.

I'm sure Richard'll say something about that and if you try to re-engineer the vaccine production without the know-how it takes

years and years and years. If you have the know-how it's still difficult but it can be done in a reasonable period of time so that's really what we're trying to work on by forming these partnerships with industry.

01:06:03

FC Dr Hatchett.

RH Thank you. I would just add - I think Mariangela and Seth have put it well - at least with respect to vaccines IP barriers are not the most important barriers to equitable access. Mariangela mentioned the capacity to scale. I would also say the capacity to deliver is critically important.

I think it is critically important to maintain a balance. If you look at the global innovation effort that has been driven in the response to the pandemic under the current intellectual property regimes without taking away intellectual property protection you see well over 200 vaccine development efforts, you see a number of companies that have worked with partners globally to provide the technology transfer, sometimes with public funding but also without.

You see tremendous investment, you see tremendous progress in developing vaccines and so you have to balance any effort to right what you think may be a wrong with what you might potentially give up and if you inhibited innovation by taking away intellectual property protections even though they're not really where vaccines are concerned the major barrier you could have unintended negative consequences.

01:07:25

I think what we're seeing through the participation in COVAX and the willingness of countries to come together in the face of a global threat is a potential pathway which, without disrupting intellectual property regimes, can provide for the kind of global simultaneous access that we all want to see.

FC Thank you, Dr Hatchett. Now I would like to give the floor again to Dr Simao for an intervention.

MS Thank you very much and thank you, Seth and Richard. I think it's important to complement the information as well because WHO has in late May launched a COVID technologies access tool because what we have seen during this pandemic is also an unprecedented move from some manufacturers in the sense of for example open-licensing their patents or for an

unprecedented sharing of scientific information on research and development which we have not seen before.

01:08:34

So WHO at the request of the Government of Costa Rica together with 40 countries has launched what we call the CTAP, a COVID Technology Access Pool. It's a voluntary pool and it's working with initiatives like the Medicines Patent Pool and with the WHO Global Observatory on Research and Development in the sense that we would like to see more of the sharing not only of the patents through voluntary mechanisms but also of the scientific information that's being developed throughout this pandemic. Thank you.

FC Thank you, Dr Simao. Dr Kate O'Brien would like to add something.

KOB I'd just like to add on the second part of your question about global public goods. I think it's really important; I think what's been addressed is the patent issue, the IP issues but SAGE and WHO have now released a values framework for how the policy which will consider these products is going to actually look at the distribution of values that will help allocate vaccines and make recommendations for populations within countries.

Given that these are global public goods it's so important for this to be a transparent process and a clear framework for how we're thinking about who gets vaccine first and who gets vaccine second, notwithstanding that the development of the vaccines is really not largely limited by these IP issues or patent issues.

01:10:18

So I think understanding each of these elements that will lead to the actual access to vaccines in an equitable and fair way that makes sense and is driven by science is really important. Thank you.

FC Thank you, Dr O'Brien. We have still a lot of questions from our journalists and not much time but I would like to give he floor to a journalist from Norway. I hope I pronounce your name well. It's Oda Skaitny from VG Norway. Oda, can you hear me?

OD Yes, I can hear you.

FC Thank you. Go ahead please.

OD Neither Russia, China or the US is on the now published list of countries that have committed to COVAX. Are you

disappointed in them and what does it mean for the success of COVAX that these countries won't participate?

01:11:15

FC Thank you, Oda. I would like to invite Dr Berkley to take this question. Dr Berkley.

SB I think it's important for us to continue to be open to vaccine producers' research and countries around the world to have them engaged and we will continue that conversation. As you've already heard articulately stated by Bruce, right now more than 70% of the world's countries are coming together. We'll see what the final number is but it may get up to the 80s or 90% and so we will work with those countries and move forward on it.

So I think that's the reality of where we are right now and at the end we want to make sure that we get to the point where everybody has access to vaccines. Of course a number of countries have decided to provide vaccines by having their own large portfolios and we gain from that as well because they invest heavily in R&D and that helps us drive forward the overall agenda.

FC Thank you, Dr Berkley. I think we will take the last question from John Cohen. John, can you hear me? John?

01:12:46

JO Yes, can you hear me?

FC Very well. Go ahead please.

JO Thank you so much for taking my call. I'm confused about a very fundamental question and it has to do with at-risk manufacturing versus the advance purchase commitments. I understand that CEPI is investing in nine vaccines for research and development but I don't understand how the COVAX facility is investing in at-risk manufacturing or if it is.

I've got one other more complicated question about monoclonal antibodies; if they work as preventives - and I realise there are access issues and supply issues and cost issues but doesn't that somehow impact this whole framework and scheme?

FC Thank you, John. I would like to invite Dr Seth Berkley to take the first question.

SB Thanks, John. I can give you a quick answer and if you want to have more discussions we can continue the discussions.

The idea of course is CEPI is investing in a number of platforms and technologies and they've been investing in multiple different components of that.

01:13:58

For the COVAX facility we are not primarily an R&D organisation but what we can do is work to make sure that technology transfers occur, that manufacturers scale up by putting incentives in place for them to do that and by paying the reservation fees for their vaccines to move forward.

Those are some of the levers that we can use as part of the effort that we have. I don't know if Richard wants to add something to that.

FC Yes, please go ahead, Dr Hatchett, if you have something to add.

RH No, just that CEPI has made a number of investments early on to support the at-risk manufacturing and then essentially are making investments to accelerate manufacturing before we have the clinical trials, just to be clear with everybody what we're talking about.

We work very closely with GAVI to think about how these manufacturing costs get allocated and who pays for them. I think that we have always viewed the manufacturing at an early a time as possible as part of the speed premium. It does increase the financial risk entailed but if one wants to have large quantities of vaccine available when the clinical trials demonstrate safety and efficacy you have to make those investments.

01:15:33

Whether they're made on the development side or made through an advance purchase agreement, either pathway can be used to facilitate that.

In terms of your question about monoclonals, John, we are all watching the monoclonal story. The therapeutics accelerator under the ACT Accelerator is making the principal investments in monoclonals at this point, not COVAX but I think going forward as we move through this pandemic but certainly into the next inter-epidemic period and as we think about preparedness for pandemics more broadly I think there's going to be a spectrum of technologies that have potential applications and benefits.

I've even started about talking about vaccine-lite technologies and monoclonals in the prophylactic capacity fall into that

category. They also have potential therapeutic applications and it's a critically important technology for us to figure out how to be ready to provide globally.

01:16:38

Hopefully further technological advances will bring the cost of goods down and make it much easier to contemplate distributing those globally. Thanks.

FC Thank you. Dr Swaminathan.

SS Just to supplement what Richard said on the monoclonals, we're looking forward to several trials that are going on now. We know of several developers of monoclonal antibodies and, John, as you very well know, these could prove to be an effective solution both for prevention as well as for treatment of early or moderate disease and late-stage disease, all of these; of course we need to wait for the results of the trials.

It cannot be a substitute for vaccines because monoclonal antibodies have a limited duration of action and would need to be repeated many times. Hopefully vaccines will offer a much longer duration of protection but as Richard said, I think we have to look at a package of interventions in order to bring the pandemic to a control both on the prevention side as well as on the therapeutics side and very importantly on the diagnostics side as well.

01:17:55

So it's going to be one more element or measure in the armamentarium that we need and finally, I think, monoclonal antibodies have a future beyond obviously this infection. There are many other infectious diseases and there are non-communicable diseases like cancer for which monoclonal antibodies are already being used and there are going to be growing indications, I think, in the future.

So this is a good time to invest in capacity for manufacture of monoclonal antibodies in the developing world so that in the future we can use this technology for multiple infectious diseases.

FC Thank you, Dr Swaminathan. Dr Aylward has something to add.

BA Yes. John, you touch on such an important point and I'm going to sound like and quote the Director-General here when he keeps saying, you have to do it all. When the ACT Accelerator was set up it was not about finding a vaccine or finding a

diagnostic or finding a therapeutic or the other measures; it was about doing all of it because, exactly as Dr Swaminathan said, we need the whole package, we need the integrated package to manage this disease, to get our health systems safe, keep the populations healthy, get our societies reopened and get the economies reopened.

01:19:15

So it's going to be that mix of vaccines, therapeutics but then Dr Swaminathan in her last point made the point of diagnostics and Mike keeps hammering this again and again and again; if we can rapidly diagnose people, they know their status, they know whether they're infected and they can then properly isolate contacts, high-risk contacts, identify... We can do so much more to control this disease today.

So if you look at the plan for the ACT Accelerator in our very first phase a big, big emphasis was on the scale-up of the diagnostics and then dexamethasone and the other interventions that are coming down the pipeline because there's a lot we can do today to be reducing morbidity and mortality of this disease much more.

FC Thank you, Dr Aylward. I think we will be closing this press conference. Before I hand over to Dr Tedros is would like to ask Dr Berkley and Dr Hatchett if they have anything they want to add. Dr Berkley, Dr Hatchett?

01:20:26

SB I want to thank everybody for the excellent questions and I want to remind people that we are moving quickly. It's an unprecedented new set of collaborations and people are working together very hard so there will be adjustments and changes.

For example one thing that I didn't comment on because my colleagues asked was why two billion doses. The answer is when we originally began to think about this we said, what's possible, what do we think is possible to be produced in 2021? We have no idea of course which vaccines will succeed, what the scale-up's going to look like, what the yield's going to look like.

So we began to plan on what we thought was possible. As we get more information those plans will change and we will have to adapt so that's going to be the challenge in front of us, trying to turn this into equitable access for all under the best science conditions but also understanding that we will not have all the answers now or even in the near future.

But thank you, everybody, for listening and we look forward to continuing the discussion with all of you.

01:21:36

FC Thank you, Dr Berkley. Dr Hatchett please, you have the floor.

RH Thank you. Just to build slightly on what Seth has said, I think we have only got this far because the entire world has been galvanised by the threats that we face. To get this far we have engaged in a very productive and ongoing set of conversations and collaborations with our industry partners, with our nongovernmental partners, with WHO and with the countries that are involved in this and many of whom have just made commitments to join the COVAX facility, which is a huge vote of confidence.

But also we have a huge vote for proceeding with this response as a collaborative, collective effort. I too want to thank all of you for joining. I've spoken obviously with many of you in the past. We are here, we do want to talk about what we're doing, we welcome your questions and we will try to be as transparent as we possibly can, recognising that we are continuing to evolve and respond to changing circumstances in a very dynamic time. Thank you.

01:22:48

FC Thank you, Dr Hatchett. Now I would like to give the floor to Dr Mike Ryan, who wants to add something.

MR I know the DG will speak to this again but I think as it is the 75th anniversary of the founding of the United Nations and as a proud staff member of WHO and someone proud to serve within the United Nations I would just want to say to our colleagues around the world, all of you out there who get up every day to serve those who have least and to preserve the peace and to fight for human rights, we thank you and we hope we can continue to serve.

We're certainly proud to be WHO, we're proud to be UN and Richard and Seth are proud to be COVAX now so we have a new flag to fly. Dag Hammarskjold, one of the great leaders of the United Nations, said the UN was not created to take the world into paradise, it was created to save the world from hell.

I think we should reflect upon the role we need to play now together as we face yet another global crisis.

FC Thank you, Dr Ryan. DG.

01:24:00

TAG Thank you. How about starting by saying happy birthday to the UN, 75th birthday. Coming to the COVAX, 64% of countries being part of COVAX is unprecedented so that's one. Many more are interested to join so we will continue the dialogue because more countries joining will really have a very positive impact for its success.

One thing which is very clear is - and we have been saying it - the partnership between countries is not because some countries are going to give charity to others. It's not a charity. It's because co-operation especially on vaccines and opening up the economy faster is in the interest of everybody.

I have said it in my speech; for the world to recover faster then it has to recover together and that's why. It's in the interest of each and every country in the world and that's what we're trying to say. Thank you so much to all journalists who have joined today and also to our colleagues, Seth and Richard, and to other colleagues who have joined us today who're working or who have been working on COVAX and on ACT Accelerator in general for the last several months. Thank you so much and see you in our next presser. Thank you.

FC Thank you, Dr Tedros. I now close this briefing and I would remind you that you will receive the audio file and the DG's opening remarks. The full transcript will be available later on and please check out the WHO GAVI and CEPI websites for more information on our theme today.

As always, I apologise to those who could not get their questions answered. Do not hesitate to contact us for any follow-up questions. Thank you so much. Au revoir.

01:27:03