Transcript of press briefing with
Dr Harvey Fineberg, Chair,
International Health Regulations Review Committee
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Speaker key
HF Dr Harvey Fineberg
MP Member of the Press

HF Yes, okay so... So I'll just say that what we had today was the fourth and the concluding plenary meeting of the review committee. That this was an opportunity for the committee to hear from member states and NGOs who are the recognised participants at the World Health Organisation, for their comments and advice based on the preview document that we distributed some weeks ago, to the member States. And the preview document represents the principle findings, conclusions and recommendations that the committee, at that time, put forward. That background document includes three principle conclusions and 15 recommendations. Can I assume that you are all familiar with it or you have seen it? So the purpose today was to give an opportunity to the member states, first and foremost, and others to give us their feedback.

I would say that we heard from, perhaps, between 12 and 20 presenters today and we've received perhaps a total of between 20 and 30 comments, either verbally or written, about the preview document. A number of the observers commented in support of one or another or all of the major ideas in the document. And so those are of great welcome to us, but they're not the ones we're focussing on now. We're looking to understand where there were questions or criticisms based on the individual states perceptions and advice to us. And now the committee's job will be to take those into account and to formulate our final report. As a general matter, I would say that the committee did its best to produce a report based on all the evidence that we had before us. That evidence consisted of extensive interviews over the last year, which many of you also witnessed, a thorough assessment of documentary evidence, written materials related to both IHR and the pandemic.

I would say that our report endeavours to be measured in both elements worthy of praise and elements worthy of criticism. And we had some of both. We wanted this report to be constructive in that it was intended to help learn lessons in a constructive way, to improvement. And we wanted it to be forward looking in laying a base for future improvements for public health emergencies and pandemics among them. Overall, I would say the comments today reinforce the major lines of our conclusions and many of the recommendations. The questions that came up were partly questions

seeking clarification or more elaboration, for example, one of the recommendations that the committee offers is a recommendation about the distribution of vaccines, in balance with the availability of viruses, the so called, open-ended discussions about virus sharing and vaccine distribution. And there were questions about exactly what did the committee mean when it said that States that received donated vaccines should adopt the same principles about liability as the States that purchase vaccines. So that was a question about that.

There was a question about the recommendation that suggested the establishment of a pre-positioned line of credit, available in the case of a future emergency, exactly where should it be located, exactly why should it be at the scale that it is, those kinds of questions that came up. There was some suggestions about elements of the report, for example, one of the recommendations indicates that in accordance with each States assessment of its priorities and benefits and costs, that we urge wider use of vaccine against seasonal influenza, as a means, both of protecting the population and of extending the capacity for production in the time of a potential pandemic. One of the suggestions today, cautioned that if you have a rationale for immunisation in anything other than the protection of the population at that time, for that... against that disease, that it could, in the long term be a weakening public confidence in such recommendations.

So there was a caution in other words, that it... don't make too much of this idea that you're recommending seasonal flu vaccines simply to prepare for a pandemic production need, when in fact the recommendation could and should stand on its own, for the protection of people, year in and year out. So that's another example of the kind of suggestion that we heard. Right now, we're going to take all of this onboard, as a committee. The whole array of these several dozen suggestions and then formulate our final report. We expect that this report will be submitted for the World Health Assembly meeting in May and presented and discussed at that meeting. We hope that the report will be actionable and practical. A report that is simply on a shelf and not translated into action is not what we intend. So let me invite your questions and I look forward to trying to respond.

MP I have one question.

HF Please.

MP Your report, can it be seen as a template on how to judge future international measures taken by WHO to fight a pandemic?

HF I would even generalise it a bit more. You know, the report has a dual character. It is, on the one side, an assessment of the international health regulations and on the other side it's an assessment of the response to this pandemic. The part of the report that deals with improving the international health regulations is the part that I think will have, year-in and year-out value. Because every year we're going to have the need to call upon the kind of resources that the international health regulations establish, in surveillance, in monitoring, in communication, responding to everything from a radiation disaster in a country to natural disaster, to a future pandemic.

So those... that side of the recommendations, I think, will have literally every day value. Now when it comes to pandemic preparedness, a lot of the recommendations, for example, the whole array of priorities for research, in understanding the predictors of virulence and spread. And the other elements that we talk about, those will be of value also for seasonal influenza, not only in the case of the next pandemic. So to an extent, on both sides, of the pandemic review and the IHR review especially, I think there will be lasting and regular value of the review. And it will also prove its worth if it does manage to strengthen preparations before a next pandemic.

MP I was wondering, in the draft report the details are lacking, at least in the end and appendix on what... maybe draw some of the conclusions, for instance, that we didn't see any malpractice or any direct links between the way the policy was formulated by the secretariat and member States and any... and no direct links with a possible conflict of interest, by industry. But at the same time, we recommend the establishment of an ethical officer to oversee these events. What was the reasoning for this? And secondly, in the final report, will there be a listing of all the people who gave evidence and their submissions attached? Thank you.

HF Let me comment on the last point. We received very extensive submissions, from many sources. We also had access to some confidential documents, from within the WHO. All of the documents which are public, that is excluding those which we had access to by virtue of our special status as a review committee, we expect will be publically available, by probably electronic means. They will not be printed in the print version of our report. So that, I think, is the way it will have public access. The full report of course, will outline in much greater detail, the basis on which the conclusions and recommendations that are in this preview document come forward. And in particular, I would just comment on this question of the conflict of interests that you raised, and the recommendations. It's impossible to prove a negative. That is, you cannot prove that there was an absence of influence. What we did say, and what we have concluded is, we could find no evidence for it. We found no direct evidence from any source and we couldn't find any indirect evidence, other than assertions by some who believe it was the only plausible explanation.

We also believe that there are alternative explanations for the actions taken, that are more plausible to us and for which we have evidence that they in fact exist. I'm referring here, for example, to the power of the public health ethic, to prevent the loss of life, as one illustration. Now, when you're thinking about the future and the protection of both the integrity and the credibility of what the World Health Organisation is called upon to do, the fact that there was no evidence of malfeasance or of inappropriate influence by industry, that we could find, does not preclude, in fact, is entirely consistent with recommendations to strengthen the approach and management of conflicts of interest, by the organisation, that we do recommend. So we're recommending it more in the spirit of good practice and prevention, than as a remedy for an error in the past. So that's the basis that we make our recommendation, with respect to the ethics officer and the other aspects of disclosure, for example, and dealing with conflict of interest. Is that a response?

MP Yes.

HF Good, okay. Other questions? Yes please, go ahead.

MP Just a follow-up question. I think you were asked some questions from the floor, about the advanced purchase pricing, but again, your report sheds no light on that. Is the final report going to provide some analysis on that aspect, which was an issue? That in earlier briefings, you highlighted, was very cumbersome and time consuming to negotiate these agreements with various providers of antivirals or vaccines. So...

HF There are two separate issues here. I don't want to conflate. The concern about the difficulty and time consuming character of negotiations in advance, referred not to national advanced purchase agreements, but rather to the World Health Organisation's effort to put in place agreements with multiple parties, that would facilitate and enable vaccine to be delivered to less well financed countries, who could not afford to purchase it. So we did not actually, as a committee, deal with the... directly with the process of negotiating in the countries that are buying vaccines for themselves, with the companies. That was not our mandate. We were very concerned with the process of negotiation around obtaining vaccine for redistribution in the world. And that was very problematic in the pandemic. It was slow, it was difficult. Interestingly, the Director General, in her remarks at the meeting today, said that in her view it was predominantly systemic obstacles that made this a difficult task.

The obstacles of the lack of harmony around regulation of vaccines, the difficulty of dealing with liability, which is a core concern of the manufacturers and the challenge of working through things like the cold chain, which had to be in place in order for donated vaccine to serve its intended purpose. So in her remark, she was emphasising again, how much effort they put into it and how hard it was. And the committee will have to take that into account in our final report, in terms of how we express what we believe can effectively be done in the future, to be more successful in this endeavour. Because everyone recognises that it remains a very serious impediment to the world's ability to deal with a future pandemic.

MP I'm sorry sir, my question was, I think, from the floor you were asked specifically about the advanced purchase pricing and there was one suggestion that, perhaps in the future, there is transparency in the prices.

HF Ah, I see, yes, no that was a separate point, yes, okay.

MP And that's not reflected in your report.

HF No.

MP The question of how countries negotiated contracts and what triggered them and whether they were commercially above board, or not.

HF Yes, we didn't deal with that in our report, because the report itself, fundamentally could not deal with reviews of individual countries. This was not the extent of our capacity to examine. It was a very interesting observation however, I would add, about the lack of information about pricing. We just didn't examine it. Yes?

MP How do you explain the basic assumption that it was necessary to buy all these doses of flu vaccine when Poland bought nothing [unclear]? Poland had one of the lowest cases of flu anywhere. Haven't you taken into account that maybe this wasn't even necessary at all and what were the initial decisions based on, in the end? And then there's also the other question, which I raised with you once before, it's the whole mindset, without talking about influence direct or indirect, it's the whole mindset that pervades the collaboration that namely anything that works with the corporate sector is going to be good, so that [unclear] don't question it. And on the contrary, we tend to facilitate it and enhance these arrangements. [Unclear] at great pains to find any, sort of, serious, obvious influence and even indirect influence, yet it's an underlying assumption that's unspoken that ropes people and shapes their behaviour. Did you take any of this into account in the end? What about Poland, how do you explain that?

HF Well let me start with the fundamental question. The committee's view is that this was a real problem. That in the beginning there was great uncertainty as to how severe it would be, and that that uncertainty persisted through the time when purchase decisions had to be made. In my view, ignoring that evidence would not have been responsible as a measure to protect the public's health. Now, it's a little bit like saying; whether fire insurance was a good idea for your house. If you look back over the last year and your house did not burn down, do you then say, I was a fool for purchasing insurance?

MP Yet at the time there were serious questions about where the information was coming from and the whole... the development of the virus in Mexico, for example, and the implications of, who did this... To avoid any investigation into how they were raising their animals and how they were providing for incubation spaces for this virus.

HF Well you're now raising a completely different and important question about the origin of influenza pandemics. And indeed many new infections, in terms of their animal origin and the mixing of animals and humans. That's a separate question. Influenza is a very versatile virus. And its capacity to simultaneously infect different species, is a very unusual property in the pathogen world. And that is one of the reasons that makes it a continually dangerous pathogen, because it has this multi species capacity and because of the changeability of its viral composition. But that's a completely different question from the validity of the evidence, early on, about real outbreaks of real disease, in a number of countries. And the committee's view is that this evidence was clear and compelling. Now on the other point that you raised, which was, did the committee think about relations to industry, or what was the point that you assume...?

MP Underlying the [overtalking] which is much more difficult to identify.

HF Well the committee had no direct view of this. I mean, to give you an illustration, if vaccines were produced by non-profit or national laboratories, the committee's attitude toward vaccine would be exactly the same as if it's produced by companies that make profit. So the attitude of the committee, toward the manufacture and distribution of the vaccine had no bearing on whether it was produced by a for-profit company.

MP Which committee?

HF My committee.

MP No, but I'm talking about previous to that, those who were in WHO were so orientated towards the corporate sector and their willingness to push in the direction of anything that will profit industry.

HF I can't even comment on the premise of your question. I have no idea that that's true.

MP I see it repeatedly, that's why I've raised the point.

HF But what does that have to do with our review, if it is true?

MP Because it's an underlying attitude that pushes in the direction of ordering huge doses of vaccine and perhaps neglecting to consider [unclear] information or whatever.

HF Well...

MP And...

HF I still can't quite see how it's connected to what our review is trying to say. If your... If the argument is that the judgements about vaccine were premised on an underlying predisposition to help companies make a profit, we could find no evidence of this.

MP Not to help them make a profit, simply to accept without questioning what they want.

HF We could find no evidence of that. The judgements about the virus, the need for a vaccine, the testing of the vaccine, the distribution of the vaccine, were not unquestioned judgements that didn't try to weigh benefits and costs. They did look at risks of vaccine; they looked at efficacy of vaccine. This was not an unthinking global acceptance of a commercial product, without any examination. So I don't understand the premise of your question.

MP My question is what I see here so often. I've seen so much over the years I've been here, since 1996, 97. That's the premise of it. On the basis, the place is invaded by industry and industry gets ahead [unclear]. And that has influence in all sorts of areas.

HF Okay, I... Well I cannot dispute it, but I cannot accept it. Okay, [unclear] do we have time for one or two more quick questions?

MP You've talked about Doctor Chan's assessment. Did you share her assessment that no amount of planning is going to change that, you said it was a serious impediment. Do you share her assessment?

HF I'm going to take it on board. That is, I'm going to try to understand the basis of her sentiment and think very carefully about what exactly could potentially have been done, even now, could be done, in advance of a next pandemic. The one thing that I would say this experience clearly demonstrated is, you cannot do very much when in the midst of the emergency. That was demonstrated by the experience. Now, the question, how much could be done in advance, the committees initial view was that you could do more. And I think we have to now think about it in light of that comment and see whether we agree or not.

MP And just, the report says... It came out a few weeks ago, so I apologise for not being completely familiar anymore, with the exact way you phrased the recommendation, in terms of the severity, re-doing the scale. What are your expectations in terms of when that should be... or the committee's expectations about when that should be out?

HF Well, I think, on the question of severity, we're... we recognise the difficulty and the complexity of the measurement. What we're saying is, first that the WHO has to face up to the need to report severity and to measure it at different stages. And I think there's not much disagreement about that, as expressed today. The tricky and difficult part will now be, okay, reduce that to actionable indicators. And that's going to take some time and continued effort. And it's not as if it's never been attempted before. But every pandemic experience gives you a better handle on how you might be able to do it. And that's what we want to take advantage of.

MP Do you have any time, does the committee...?

HF The committee didn't say it has to be done, you know, within a year or within six months or two years. But I do think that it's going to take months and probably the better part of a year or two, to really nail this down. That's my estimate, but that's not what the committee is specifying. It's not something you can just turn around and pull out of a drawer. Any final question? Well thank you all very much. Yes, you have...? All right, we almost got done. We'll take one more... a quick one.

MP Coming back to Doctor Chan's comments, she left no stone unturned to try and get the donated vaccines to countries that didn't have the capacity. Some industry representatives said to us that some of the donations were available months in advance to WHO and did not go out to the potential recipient States. Today's version, from Doctor Chan is another interpretation. What did your insights show?

HF Yes, first the companies differed in their willingness to enter agreements. There was some negotiation that was difficult, but concluded successfully. There was other that was relatively easy and there was some that never concluded. So on the question of the readiness of companies to participate, there was a spectrum. On the question of getting the vaccine actually into the hands of doctors, nurses and other administrators in the country, you have still all of these issues about the cold chain and about the regulations in the country and approvals locally that Doctor Chan also indicated were significant obstacles.

And so it's very easy to imagine the circumstance where a representative of a company that was readily, relatively willing to contribute, would find themselves in

an observation of delay, because of these other factors that are country specific, in getting the vaccine out. So you can see how you could reconcile those perspectives on the question of getting the vaccine to the recipient countries. And it underscores the complexity of it. I would say it also underscores the importance of advance arrangements insofar as they can be accomplished. So, I think, with that I thank you all and I look forward perhaps to see some of you at the World Health Assembly, or no...

MP Of course.

HF Of course, and we'll see how the discussion is at that venue.

MP And useful from our point of view I think.