Transcript of press briefing at Palais is de Nations, Geneva
Dr Harvey Fineberg, Chair,
International Health Regulations Review Committee

19 May 2010

(NOTE: sound quality of the audio file was poor in places as noted in the transcript)

Harvey Fineberg:

Good afternoon everyone. I'm Harvey Fineberg. I'm the chair of the committee to review the function of the IHR (International Health Regulations), and the H1N1 pandemic experience. I am pleased to have this opportunity to meet with you and to try to respond to any questions that you may have.

Many of you I know, are aware that the committee was formed earlier this year. That we had our first meeting here in Geneva, approximately a month ago, and that our second meeting is anticipated to be held at end of June and the first two days of July.

We are here represented by myself in order to hear and participate in the portions of the World Health Assembly, that is related to IHR and influenza, and also as all of you know, from being here, it is a marvelous opportunity to see a great many people and to have interactions informally as well as in formal ways.

But today, I am pleased to be able to be with you, and to be able to respond to any questions that you may have about the work of our Review Committee (RC). So with that, let me invite any questions from those who are here.

German Press Agency:

How much are you actually investigating the issue of the WHO's links with industry? How much has that really taken up time and efforts from your committee?
Harvey Fineberg:

The committee is well aware that there is concern that has been expressed about the potential influence of industry on decision-making at the various advisory committees and in the WHO more generally.

We began to explore this issue with some discussions at the plenary sessions, even at our first meeting, hearing from the chairs of the SAGE committee, this is the vaccine strategy committee, and also from the Emergency Committee chair, who dealt with decisions about the pandemic. We expect very much to continue this exploration including discussions with representatives from the industry side, and we are very attentive to try to understand and to identify the nature of any relations, the degrees of influence as may have existed and the basis for that, and also to take account of that in conclusions and recommendations. As of this time, we are still in the information gathering phase. I would add if I may that, if any of you has information about the relations that you feel may be helpful to the committee, we are very eager to receive that information, and it can be in the form of materials that you have or communications that you are aware of, or people that you believe would be helpful for us to learn from, any of that would be very welcome. Would you like to follow-up?

German Press Agency:

If you were to find the link, what would that lead to, and would that lead to a more general review of WHO's link to industry?

Harvey Fineberg:

What do you mean by find a link?

German Press Agency:

Well, you say the degrees of influence that may have existed, let's say there are degrees of influence in some form.

Harvey Fineberg:

It's a hypothetical of course, but let us presume for a moment the premise of your question, what if there were, would that have wider implications? If it did exist, then our committee is fully authorize to make recommendations to the Director-General, to the State parties, the constituents, who are responsible for the agreement of the IHR, to take appropriate action as we deem it to be indicated. So there is no restriction on our committee in the nature of the recommendations that may follow from our conclusions.

Frank Jordans, Associated Press:

You said there are no restrictions on the nature of the recommendations. Can you tell us if there are any restrictions on where you can publish the recommendations ---?
Harvey Fineberg:

Well this committee is a committee whose report, formally, will go the Director-General, and the Director-General will transmit a report and potentially additional comments of her own to the World Health Assembly next year. That is the plan.

I have been assured personally, that the report of the committee, in its entirety, will be a public document. So I expect that that will be the case. That does not mean that the DG will accept every word of the document. But it does mean that the committee is assured that its conclusions and recommendations will be a matter of public record.

Robert Parsons, Geneva Courier:

Dr Chan told the Executive Board in January there was no problem in WHO's handling of the H1N1 pandemic, that the whole problem was simply media and people seeking sensationalism and lies and whatever. Are you going to pursue the aspect that, are you going to look into that considering that was her official statement to the Members of the Executive Board, that it actually all lies with the media, and that the media had --- it and ---- .sensationalism seeking to sell newspapers and so on.

Harvey Fineberg:

I was not present at the time the DG made that comment, but I can tell you what she has said to me, and to our committee, and in her approach to us she has explained consistently that she wants an open, honest, and transparent assessment as objectively as we can make it about what happened, what was done well, what was done poorly, and the aim in all of it is to identify lessons to improve performance in the future.

This is not to exonerate the role of the media, but it is also not diminish the responsibilities for what went well and what went poorly, in decisions, and in actions at the WHO and at Member States. Our committee is mandated to look in any aspect of the experience that we think bears on lessons for the future.

Just a personal aside, even if you believed that the nature of the reporting about the pandemic in particular instances was a problem, then it suggests to me that you need to face up to the importance and working more effectively with the media and in reaching the public so that accurate, timely, relevant information conveyed in a correct way that is correct in terms of its implications, in terms of the context, or in terms of what means for health and what it means for society, that all of that is done in a successful way. And if the inquiry that we are undertaking leads us to that direction of the importance of the media and the role of the media, it does not mean that there is a fault in the media in my mind. It simply means that the process of conveying and reaching that public was deficient in one way or another, and that can be approached in many ways. So it's not to me a matter of looking at the media as a source of a problem. The media is a vital conduit between experts and policy makers and the public and vice versa.
Robert Parsons, Geneva Courier:

Yes because the WHO spokesperson has denied that the WHO changed the definition of a pandemic, yet the 2005 guidelines on the WHO web site, they were sent out to Member States are at variance with what was used to define the pandemic. For example, 7 some million deaths in a very short period of time --- hundreds of millions of hospitalizations ---. How do you intend to deal with this? Will you take this into account or is it a fact that there was no change in definition?

Harvey Fineberg:

The question of the characterization of a pandemic and how the practices about the characterization may have varied over time and for what reasons, all of this is a very important part of the understanding that the committee has to reach. So we are very much attending to this set of questions around the way a pandemic is described and characterized. You mentioned the historical feature of how it may have been different one and time and changed in another time that is one dimension of this. But another very important dimension implicit in that and certainly important looking ahead is the question of characterizing severity as well as extent. So that you have pandemic spreading how quickly, is a different question from whether and to what degree it is producing deaths, illness and other problems. And the committee is going to have to come with grips with all of these aspects of the characterization: historic, and this question of severity, as well as spread.

John Zaracostas, British Medical Journal:

You mentioned that you have assurances that your report will be a public document. Will that included all the material forwarded to the committees: epidemiological data, etc? Will that be included as attachments in annexes? Because during the first year, a lot of these epidemiological data that was coming in to the WHO from Mexico, the US, Canada, was certainly not shared with the media. Thank you.

Harvey Fineberg:

In response to the question, first the report itself will be public. The report is going to be likely a document that will include a number of annexes which will range across the relevant but not intrinsically important material contained within the report. So there will be a number of annexes. We have not as a committee yet developed a full conclusion about accessibility to additional materials as may be for example web based. But one thing I could say that we are aware we will want to have access to certain confidential documents that may be in place here at WHO or elsewhere. And by virtue of our examining them, they do not automatically become public documents. So there will be some materials I know we will be looking at.

John Zaracostas, British Medical Journal:

Epidemiological documents, hard science…
Harvey Fineberg:

Yes, I do not know the answer to what the policy is about that. But I am confident that we will have access to all of that information. What I can answer is whether it is or is not part of the public record or would be become part of the public record, I just do not know.

Lisa Schlein, Voice of America:

Once you have finished your investigation, will, among the answers, will there be answers to the question or the criticism that perhaps this whole pandemic has been over-blown? And how do you actually evaluate whether, indeed, it may have been over-blown or not?

Harvey Fineberg:

The question of whether a pandemic is over-blown is connected to the earlier point about the characterization of a pandemic. When you are approaching this question, how do you decide? Even though we are looking back at the experience, the important posture is to take a proactive point of view, namely what was it what was known at a particular point in time when a decision was made about a certain character of the pandemic. And what we want to avoid as a committee is applying a, what I will call, a mindless retrospective view which is simply saying, well we learned this much happened afterwards, why did not they understand what was going to happen when the reality in prospect is that uncertainty of a situation may have been very much more prominent than later resolved into a reality.

So the characterization of the choices made as insufficient, appropriate, over-blown, or something, will always have to be taken from this prospective posture understanding what was known, and I should add, what was knowable, because it is also possible that information at that time was not availed of, that could have better informed the decision. That is very different from information that only became evident at some subsequent time and could not have influenced the earlier choice. So that is how we are going to try to approach the question.

To do that, you really have to have a very fundamental understanding of what was known at what point in time. And so part of the work of the committee with the help of our Secretariat is identifying the sequence of events and information, so that we can make our judgments about the choices made based on the actual knowledge at that time.

Neue Zurcher Zeitung (NZZ):

--- in the language of tabloids, what happened was that some experts from the pharma industry somehow worked on the WHO and -- made --- this pandemic -- made suggest that the pharma industry goes ahead producing much vaccines and making a lot of money -- if you go the bottom of the scene the interface is the experts. The committee wants cutting-edge knowledge about research about pandemic and vaccines, etc., so somehow it wants to be as close as possible to the research which has been done by the industry, because they have the money to do it. And there you sort of establish an intrinsic link, and may be a linkage of interests. How do you tackle this?
Harvey Fineberg:

Let me talk about the general point and then come to the application, if you will, to this instance.

As a general point, any time you have an expert advisory committee, you are trying to keep in mind two things. One is you do need people who actually have expertise, so that means the experience, the training, the professional knowledge, that is relevant to the task. And secondly, you want to keep the committee as free of possible from a conflict of interest, which is in the terms I'm using, a financial interest in the outcome that follows.

And so when you look at the qualifications of individual participants in such activities as expert advisory groups, you really have to ask the question, are they experts and were they conflicted? Two questions.

This is now coming to the specific. I do not yet know what the judgment would be looking at any individual members of the decision-making bodies. But I do think that it's a relevant question for our committee to examine. Because it does get to the heart of this allegation about undue influence from industry.

What I can tell you if you go back to the first meeting, the chairs at least of both the SAGE and the expert advisory group were quite adamant and straightforward in rejecting any direct influence by industry on any part of their decision-making as far as they could know. But I realize you are raising a more subtle and slightly different point which is not whether the industry came in and made undue influence directly but whether the individuals who were part of the process already brought with them, a predisposition to make decisions that would be in the interest of the companies. And we have to look into this.

Stephanie Nebehay, Reuters:

Has the WHO Secretariat began to share with you already the experts who -- have they began to share with you confidential documents on the early part of the process --- ?

Harvey Fineberg:

What I can say is that, any document that we have requested they have made available to us. What I cannot tell you because I do not really know whether anything we have been shown was at some point considered confidential or still is. So I cannot specifically respond to your question. But I can tell you that the Secretariat is being extremely forthcoming in making available to the committee all materials that we have requested. And in fact, they are going beyond that because literally this morning, I had an opportunity to meet with a number of representatives of the Secretariat of the relevant clusters here at WHO. And they are providing additional materials that are in a way compiled and made available for the benefit of the committee beyond even what was already in place. So we are getting access to everything that we have asked for, pre-existing information, and even more.
Gunilla von Hall, Svenska Dagbladet:

--- you will take appropriate action to recommend appropriate action. What does that mean?

Harvey Fineberg:

Well concretely, it depends on the nature of the link, which is why I ask my question, what do you mean by a link?

What I would say as a general matter, we want to offer recommendations that are key to the problems we find. We want to offer recommendations that enable the world, WHO, and the nations to do better the next time, and we are confident there will be a next time, at some point.

So what exactly would we say under hypothetical finding is really too hard to answer concretely. It depends. And what I would say as you follow the process, as I hope you will, and as you see the nature of our findings and conclusions, you will be able to judge, whether the recommendations that have followed are indeed appropriate to the findings and conclusions, and that will be a matter of judgment that I hope you will exercise.

Frank Jordans, AP:

To your knowledge, what kind of documents are classified documents?

Harvey Fineberg:

The only ones that I am personally aware is that some of the agreements with industry that we would like to examine have been considered confidential agreements. And I do not really know more about that at this point, but that is what I understand, that's what I meant by confidential documents. I did not have in mind epidemiological data.

Stephanie Nebehay, Reuters:

So the documents are referring to donations or --- ?

Harvey Fineberg:

No, no. You may be right that there other kinds of documents that are confidential that am not aware that they are confidential. But the ones that I was aware of in response to this question are some either contractual or letters of understanding with industry that have been considered private communications.

Lisa Schlein, Voice of America:

I was wondering, the next meeting that you are having at the end of next month. What is the next level of work that you will be doing that is what particularly will you be probing which is different from here, or moving the process?
Harvey Fineberg:

As some of you are aware in our first meeting's conclusion, we decided that we were going to proceed really along five tracks in terms of our work plan. Three of the tracks dealt with the kind of sequence of H1N1 response starting with the preparedness then the question of alert and then the question of response. So those were three of the tracks.

The fourth is a cross-cutting track of communication, that gets to the question about the media, but communications in its broadest sense as many actors, many communicators, many communicated-to, and understanding the responsibilities and the actions at all of those levels.

And the fifth was the IHR regulations and its performance with some special reference to experiences in addition to the H1N1 because H1N1 is also a kind of test case for the IHR. So what the committee has done, in the course of the interval between our first meeting and our second, is try to work in sub-groups, attempting to enumerate the key issues that we need to explore in these five areas. And that's, part of that process is elaborating issues and part of the process is winnowing the issues to the one that are really important.

And then what we hope to accomplish at our second meeting, is particularly to include in the plenary sessions, of the second meeting, the opportunity to hear from witnesses to the committee individual with competencies one way or another of the areas that we consider important that we want to make for the injury. So for example, some of the issues we have already raised around the industry and its influence, or around the definition and characterization of a pandemic, and potential around communications questions. All of these could be a part of the agenda for this next meeting.

We are still in the process of refining the issues to know which of the ones that we are concerned about. Do we want to put the highest order priority for the precious time we have together on these three days, June 30, July 1 and 2, and that we are going to do.

I might add here when it comes to the meeting, the next meeting, what I am going to propose to the committee is that in the plenary sessions of the meeting, we once again open the meeting to the press. As you know, we took this step in the first meeting. I think it was good choice then, and am hoping that the committee will go along with that in our next meeting, but I emphasize at this point that it will be a proposal that I will make to the committee and the choice will be at that time.

Lisa Schlein, Voice of America:

Sorry are there 18 members?

Harvey Fineberg:

No, there are 29 members appointed to the committee at this time.
Isabel Saco, EFE:

At this point do you think that there will be --- when do you think you could be able to give some conclusions and advice on the recommendations?

Harvey Fineberg:

Our aim is to have the report presented to next year's World Health Assembly. So that's really the target.

We have discovered that these are very complicated issues, some of them, and my hope is that we will be able to complete all of our fundamental assessments in that time frame. But another point that the Director-General has made clear to us is that, whatever the committee requires, in time and effort to do its job thoroughly as well as fairly, she will endeavor to make available to us. But our goal is to have the report presented a year from now.

Isabel Saco, EFE:

So not really to have some really in-depth information from you before that date?

Harvey Fineberg:

I would say, that is correct.

Question:

You said you would --- witnesses to the committee. Who are you talking about, witnesses?

Harvey Fineberg:

I mean experts or individuals. Witness is may be too legalistic a term, but its people who will be called to offer their views. Individuals that we will invite to come to Geneva to help us to understand something, and the something could be definitions of pandemic, it could be the role of industry, and it could be a number of these key issues. That is what I meant. Thank you for the opportunity to clarify.

John Zaracostas, BMJ:

I was wondering, sir, if you can elaborate, how can you deal with the situation that in your committee, you have members who are part of the Emergency Committee that was instrumental beginning from the various phases? What are the terms of reference and in what areas will they step back and be unable to comment and at the end of your report, will these members be identified and will the report been written in a way that each intervention by a member of the committee can be identified or will it anonymous??
Harvey Fineberg:

Let me get to the last question first. In general, the report will be a report of the committee. Every member of the committee will have an opportunity if they dissent from any part of the report to offer their dissenting position. So that will be a part of this. If there is any part of the report from which members of the committee for any reason, and I stress any reason because, let me come back to why I say that, is recused, then that will be explicitly explained also in the report.

When I say for any reason many members of this committee including myself, have played some kinds of role in respect to H1N1 nationally or internationally over the course of the epidemic, so I think it is quite important that all members of the committee understand that background and experience of all of us, so that the committee can know in effect what each of us brings by way of that experience and background to the deliberations. And I will tell you that we are aware, we became aware, those of us who were appointed to the committee of the, let me say, joint roles, that some have played for other WHO committees as well as our review and we are very mindful of needing to come to grips with that, but I believe it is a more general problem that we also have to understand and approach and because it could be that there are many different ways in which any of us could bring predispositions to this, and we want to expose that and make sure that we within the committee are fully cognizant and aware of it.

John Zaracostas, BMJ:

If I can rephrase my question, for instance, on the segment concerning the phasing. If you have got members of your committee that were instrumental in the decision--making for this segment, will they step back and say, look I cannot offer an opinion here because, I was, you cannot be judge jury if you are a decision maker on going from five to six you can't be a critic and review a decision. That is just basic jurisprudence, is not it?

Harvey Fineberg:

Let me state it a little more generally and essentially to your point.

I agree, you cannot serve effectively as both the actor and the judge. So I think in such instances which may apply in a number of different circumstances. I will give you an example personally.

If there were, if the committee were to make some judgments about decisions taking in the United States where I live, and where I served in an informal role about advising the US Centers for Diseases Control, the was some question about relationship between that agency and WHO at some point. Then that would be a topic and an issue where I personally would feel, I would need to at the minimum explain it to my fellow committee members and if it were an issue where I played a role in a decision, I would have to recues myself.

So I think the logic of this recusal process would apply across the board to anyone who has a joint role so to speak on any matter that would be coming before the committee.
Gabriella Sotomayor, Mexican News Agency:

Something is not clear to me. Are you going to review the industry, are you going to investigate them, or only WHO and its Member States?

Harvey Fineberg:

Let me be clear on this. We are not here to investigate the decisions taken by industry per se. So for example, let me just give you a hypothetical.

Industry decides to have built a factory in a particular place and not in another to produce vaccine. Why did they do that? Why did they build it there? We have no mandate to investigate. Why was industry better prepared in place X or in place Y? That is beyond our scope.

But when it comes to the relationship of industry to decision-making, in the course of this pandemic, then that is relevant to us. And so we are not investigating industry, we are investigating a set of decisions with all of the relevant actors as each decision took place. So that will be our guide.

Gabriella Sotomayor, Mexican News Agency:

--- are you going to follow the money?

Harvey Fineberg:

Well, I suppose in general it is a good advice, but I'm not sure, you mean, to see who made money from this entire episode and there fore what did that mean? It is not a bad strategy. I do not know that it will be a complete strategy for us because there is so much of this that in a way surrounds and precedes the money. I think that, I understand that there is a tendency, one of you said before, you know, to read a typical news paper, this is a simple line of the story. People made decisions to produce money for particular businesses and we have to take that seriously. But I don't think that it is a good complete strategy for our inquiry.

Stephanie Nebehay, Reuters:

--- how many of the Review Committee members -- ?

Harvey Fineberg:

Let me say that the, what my position is, is that every member of our committee, of this committee, must reveal their associations to the committee. Now what will be the decision about that depends again, contextually, on what was the specific association or role I revealed mine here, but it may be different for different people.
Question:

-- are you still not aware of how many --- ?

Harvey Fineberg:

I will say that I was not aware before the first meeting of any and so I learned at the first meeting also about the dual positions of some persons. I am told that it is more than Dr MacKenzie. So these are things that we have to attend to.

Question:

--- ?

Harvey Fineberg:

I do not think we have formally extended invitations as yet, but I can tell you that we are very interested in hearing directly from representatives of the industry. Now who exactly it will be, I cannot tell you at this moment, but this is of great interest to the committee.

Robert Parsons, Geneva Courier:

A communication question: there were reports from Mexico that said that illnesses of influenza were actually the results of --- conditions of pig farms there --- are you going to look into the aspect of --- not verified --- ? Are you in touch with the --- Council of Europe that is investigating this?

Harvey Fineberg:

We are aware of a number of national investigations, about the performance of the individual country on H1N1. Japan, for example, spoke of the inquiry that they are doing and their presentation at the World Health Assembly. We hope to take full advantage of all of these.

I do not know the exact status of a Mexican review or its performance, but I would say that the kind of detailed question that you are raising at the outset on choices made in Mexico would be more a matter of a national review of Mexico than it would for our committee to undertake.

There are details of management, use of information, decision-making, in every country that dealt with this which is just about every country. But that is beyond the --- of this committee.

Thank you all very much.