Gregory Hartl: Good afternoon. It is just gone one o'clock in Geneva. We are coming to you from the WHO in Geneva, and it is the 18th of February. Welcome to our weekly virtual press briefing. With us is Dr Keiji Fukuda, the Special Adviser to the Director-General for Pandemic Influenza, and just before I hand over to Dr Fukuda, could I remind you please that you will find shortly after this press briefing, an audio file and a written transcript of this briefing on the WHO website, that is www.who.int. Callers who would like to ask a question, please dial 01 on the keypad to get into the queue and now, we will now hand over to Dr Fukuda. Thank you.

Dr Fukuda: Hello everybody, and welcome to this virtual press conference from WHO. As usual, let me briefly update you on the current disease activity and then talk about some more recent issues which I think will be of interest.

In terms of the epidemiologic activity, it is very similar to what we reported last week, in which we have seen the highest levels of activities occurring in parts of Eastern Europe, some parts of Northern Africa and parts of Asia. And then similarly, as I reported last week, we first started seeing reports of community-level transmission in Western Africa, in Senegal.

And this week, we continue to see reports of community transmission but also in Mauritania. So we continue to see activity in Western Africa.

Now yesterday, we concluded a four-day meeting which was to look at vaccine strains for influenza vaccine for the 2010 and 2011 season. And we just concluded the public announcement for these strains a little while ago. And so what I would like to do is both review the process a little bit, and then go over the recommendations and the implications of the recommendations.

WHO routinely holds a consultation twice a year, with advisers from WHO collaborating centers and a group of national regulatory authorities to recommend influenza vaccines strains to be used in the northern hemisphere vaccine, and then in a separate meeting for the southern hemisphere.
It is the advisers from these organizations who provide formal advice to WHO on which strains should go into the vaccines. But also at the meeting, there are a number of observers, and these are generally directors from national influenza centers as well as representatives of other technical organizations who come and sometimes provide input and joining in the discussions. However, the observers themselves do not provided the formal input to WHO.

I do want to point out that there are no representatives from industry who partake either as observers or as advisers in these meetings.

Now these consultations which are held twice a year, built upon a series of telephone conferences and other consultations which take place, building up to the face-to-face meeting. And in these consultations which take place before in the meeting as well as this meeting, the scientists who are there go over a large amount of data, and a variety of data. They go over analysis of the viruses, but they also review what the epidemiological picture is and what the clinical impact of these viruses are. And all of this information is taken together to help make recommendations to WHO about what should go into the influenza vaccine.

Now following the recommendation, we hold a public meeting at which anybody who wishes to come may attend. So this public meeting just concluded about 30 minutes ago. And typically at the public session, we often have representatives of industry, representatives from media, and then as well as other interested parties, in understanding what is the most recent picture about the influenza viruses and why, what is the basis for the recommendations that are made.

At the public meeting, we release the information about the formal recommendations and so this goes to all vaccine manufacturers at the same time and the report is put on the web. So it can be seen by anybody. And this is done as soon as the recommendations are made and during the meeting itself.

Also at the meeting, this offers a time for representatives from industry as well as other people to ask questions of the advisers providing the advice. And frequently there is back and forth asking some questions about different aspects of the decision making and the discussions.

Now this year's consultation for the northern hemisphere vaccine, and this was a meeting again to decide what should go into the vaccine for this coming fall and winter in the northern hemisphere. The meeting took four days, and the discussions went very well. The bottom line for the discussions were that we are recommending that the pandemic influenza H1N1 virus go into vaccine for the coming fall and winter in the northern hemisphere. And the consultation is also recommending that there will be a representative H3N2 virus and a B virus. And so these are three viruses being recommended for the coming vaccine.

Now the specific recommendations themselves can be seen on the web, and it is a quite technical group of names, but one of them is A California virus, which is the pandemic virus. The second one is an A Perth virus which is the influenza A H3N2 virus. And then the third virus is the B Brisbane virus which is the third component.
Now this is a very technical discussion and sometimes the information is hard to understand. So let me try to put the discussions and recommendations in a little perspective and try to make it easier to understand.

In essence, in the discussions, what the scientists said was that in the past year, the overwhelming number of influenza viruses that were isolated around the world were the pandemic H1N1 virus. The experts believe based on this information that these viruses will continue to be one of the dominant viruses in wide circulation in the coming fall and winter season in the northern hemisphere. And this is why they are recommending that this virus be put into vaccines for the fall and winter times.

At the same time they looked at the data and they said that the older H1 viruses, the seasonal H1N1 viruses were found very infrequently. And again based on that information, they believe that the seasonal viruses, even if they persist, will not pose a major or significant public health risk to people. And so that virus was not recommended to go into the upcoming vaccine.

The scientist also noted that the seasonal H3N2 viruses and the B viruses were isolated at a much lower rate than the pandemic viruses. However, they were persistent through the year and, in fact, in some countries we are seeing an increase of activity of the H3N2 and B viruses. And so based on this, the scientist concluded that these viruses will continue to pose a significant public health risk to people. And so they recommended that these viruses go into vaccine for the coming year.

Now based on this, let me anticipate one major question which is, does this recommendation or putting the pandemic virus in the vaccine, mean that the pandemic is over? And so let me be very clear. The recommendation to put the pandemic virus into the vaccine for the fall and winter is really a separate issue from whether the pandemic is over. So no, this recommendation does not indicate that the pandemic is over. And the replacement of the seasonal H1N1 virus by the pandemic virus also does not signal that the pandemic is over. Again to underscore this point, the recommendation to put the pandemic virus in the upcoming vaccine really means that this has been a dominant virus. And it is expected that it will continue to be a significant virus, circulating around the world as we head into the winter or the coming winter in 2010 and 2011.

So to underscore this main point and circle back to it, at this point we have to say that the pandemic is not over. However, as I discussed last week and as many of you are aware, WHO will be convening the Emergency Committee under the International Health Regulations (IHR) and this will take place next Tuesday. And this committee will be meeting both to review the overall epidemiologic and virologic situation, and to provide some guidance to WHO as to whether we can consider ourselves in the so-called post-peak period. The post-peak period as indicated in the guidance which was provided to countries before the pandemic occurred, is a transition period in which we continue to expect to see pandemic activity occur at different levels in different parts of the world. But we hope that the worst is behind us and that the overall trend will be going down. So again the post-peak period means that we continue to be in a pandemic. However, we hope that we are transitioning down to a more normal period.

Now, I think that as we begin to transition, one of the important points which I hope is very clear is that we can still expect to see significant levels of activity or perhaps outbreaks occurring in different countries. And here I think that the first report of community transmission occurring in
places such as Senegal and Mauritania, is a very good reminder that what we are seeing in some parts of the world, for example Europe or north America, is not necessarily what we will be seeing in other parts of the world at the same time. We really expect that there will be different levels of activity in different parts of the world.

So at this point, WHO considers vaccination against the pandemic virus to be very important. We continue to see this virus in wide circulation. We continue to see that there are a number of people who are at risk for developing severe complications from infections by the pandemic virus. And that the vaccine can offer good protection for these people.

So to remind everybody again that there are certain groups, for example pregnant women, younger people, and especially younger people with chronic medical conditions who are at higher risk than other people for developing severe complications from infections by this virus.

So to summarize here, let me point out that the ending of a pandemic is not an on and off phenomenon, we really expected it to be more of a tailing off phenomenon in which there will be a transition back to a more normal period but it is not an on and off phenomenon, it does not happen overnight. The inclusion of the H1N1 pandemic virus in the influenza vaccine does not signal that the pandemic is over rather the right interpretation of it is to say that this virus is expected to be a significant threat to people as we go into next year's fall and winter period and therefore protecting people against it in the vaccine is the basis for that decision.

Another point is that WHO continues to recommend vaccination for people and especially for certain groups of people such as healthcare workers and people at higher risk for developing complications such as pregnant women, and people with chronic medical conditions.

Finally, next week we will be holding discussions with the Emergency Committee as to whether we may be in a post peak period and if such a determination is made we would still like to point out that WHO will be working closely with countries to make recommendations and take all possible steps to help protect people against this pandemic infection. With that let's go on to questions and I am happy to entertain whatever you have to ask. Thank you.

G. Hartl: Before we go to questions if there are any, I would invite journalists to dial 01 on the keypad if they would like to ask a question and to remind journalists that shortly after the end of the press conference an audio file will be available on the WHO website, www.who.int and that the later in the day we will also have a written transcript. So the first question is from Bloomberg in London, go ahead please:

Bloomberg: Do you anticipate that vaccine manufacturers will continue to manufacture separate pandemic vaccine for very long or to stop production of it. Is there still a need for it now that H1N1 is included in the seasonal flu vaccine and can people who are already vaccinated against H1N1 also get the seasonal flu vaccine containing H1N1 in 2010 with no consequences?

Dr Fukuda: These are very good questions. I think that the final decisions about what kind of influenza vaccines should be made, whether we should continue to have monovalent vaccine or just a trivalent vaccine that is vaccines containing the three viruses or whether there should be a
combination of these are decided by countries and in meetings held with the national regulatory authorities.

In addition, however, in April WHO meets with its SAGE Committee - the Strategic Advisory Group of Experts - who provide immunization advice. They will also discuss whether we should be making one vaccine or the other or both types of vaccines. I think that the most important part of this question is that it is possible that as we eventually transition back to a more seasonal picture around the world that this pandemic virus may continue to pose some risk for groups which often do not get vaccinated. That is, younger people and oftentimes women who are pregnant and so I think that one of the questions that has to get looked at is whether there will be additional need for monovalent vaccine in some countries to help provide protection to groups that do not often get vaccinated against seasonal influenza so I think that this discussion is not completed yet and we will see what the recommendations are coming out of some of the countries as well as SAGE.

Now in terms of the question on whether getting vaccinated with seasonal trivalent vaccine in the fall time if you have already gotten vaccinated with pandemic vaccine poses any unusual risk or any danger. With the current pandemic vaccine, we have now seen that over 200 million have gotten vaccinated with this vaccine. The monitoring for side effects and adverse effects have been unusually high and the reporting and the monitoring and the assessing of the safety events, any reported safety events, has been unusually high and what we have seen is that there have been no unusual reports of unexpected adverse effects or side effects and in general the safety profile of these vaccines has been excellent, comparable to seasonal vaccines or perhaps even a little bit better. Right now we have no evidence to suggest or no reason to suspect that getting vaccinated with the trivalent seasonal vaccine - even if you have been vaccinated earlier with the pandemic vaccine - should cause any problems at all. Thank you.

G. Hartl: Thank you very much. The next question is from Maria Cheng, Associated Press London. Go ahead Maria please.

Maria Cheng, Associated Press London: Hi, thanks for taking my question. I wanted to ask if WHO has worked out the criteria for determining when the pandemic is over. Dr Fukuda, you said that it would not be an on and off phenomenon, I'm just wondering if you have identified what markers you will be looking for or if that is something that the Emergency Committee will be discussing next week.

Dr Fukuda: Thank you for this question. Maria, when we look at the guidance which was provided to countries in the 2009 Preparedness Guidelines, what those Guidelines discuss is the post peak period which is the transition period as well as the post-pandemic period which signifies when we have a quite good expectation that we are really getting close to the normal period and out of the pandemic period. I think that similar to the discussions on the post peak period we will be meeting with the Emergency Committee and asking for their advice and also using the criteria provide in the Guidelines as to whether we are in a post-pandemic period. I think that these discussions will take place in the future. Unless the Emergency Committee brings this up we are expecting to hear more from them about the post peak period but I anticipate that in the future of course we will be taking about the post-pandemic period. Thank you.
G. Hartl: Thank you. Before we move to the next question, can I remind journalists again that if you wish to ask a question, dial 01 on your keypad. Next question is from Miriam Falco of CNN - go ahead please.

No reply

G. Hartl: Sorry, we will have to go to another questioner. Richard Knox from NPR, go ahead please.

R. Knox: Thank you very much. I wonder if you could talk a little bit about the practical effect of declaring a post peak period or phase would be - what happens if that is decided?

Dr Fukuda: The practical effect of indicating that we are in a post peak period is really to give a broad signal to the world that even though we may continue to see pandemic activity that we expect that we are transitioning more towards a normal level. I think this gives a heads up to countries about needing to plan ahead and to take a look at any measures that they are taking that they have in effect and whether they want to begin changing any of those measures. It really will be a good signal for countries as to planning for when they are going to transition back into a post-pandemic period. That's probably the most practical effect but also it will push us all to look at what different recommendations may be needed, whether there are any different activities which are needed to put in place as we transition back to a post-pandemic period. So that is probably the most practical effect of such an indication. Thank you.

G. Hartl: Thank you very much. The next question comes from Asahi Shimbun. And before we go to the actual question, again journalists who wish to ask a question dial 01 on their keypad. Over to you Asashi Shimbun please.

AS: Hello, thank you very much for taking my question. I am wondering this WHO recommendation composition for influenza vaccine means that pandemic influenza has become one of the seasonal influenza?

Dr Fukuda: I think the best interpretation again is - or the most helpful way to think about this is to keep the recommendation for the vaccines separate from the question of whether we are in a pandemic or not. If we look at the information which we have on the viruses and the disease patterns in the world, this information here tells us that we should expect that the pandemic H1N1 virus is still going to be widely circulating in the fall time, in the winter time, and that's why we ought to put it into the vaccines.

On a separate note, what we will be doing is taking a look at the disease patterns around the world, trying to monitor how the levels are going and trying to determine whether there is any information suggesting that we are really trending downwards and we should not be expecting any major upsurges in activity. Then on the basis of that kind of analysis decide when we should be calling for or declaring a non-pandemic period. So the vaccine decisions does not tell us whether we are in a pandemic or not, they really give us guidance on how to protect people and then separately we will be looking at all available epidemiologic information and viral information to decide whether we are moving out of the pandemic or not. Thank you.
G. Hartl: Thank you very much. Richard Knox has a follow-up question, if we can go to Mr. Knox please.

Richard Knox: I didn't but I can probably think of one. I think you mentioned this before but I would like to be little bit clearer - do you expect at this point that the same people who were most at risk for infections with the pandemic virus in the past 10 months that is to say a younger demographic than we see in normal flu seasons will be at risk in the next fall and winter and therefore that that group should be targeted for vaccination and perhaps older people not.

Dr Fukuda: That is a very interesting and I think very difficult question. I think that it would be surprising if we see a very abrupt change in who is at risk from this virus. I think that even as the virus begins to mutate and change over time, it has established to some extent who is at risk for developing severe complications from it. Now, one of the difficult parts of your question is that the people who get very sick from this pandemic virus tend to get very sick in a way which is different from some of the other influenza viruses, the other seasonal influenza viruses because the pandemic virus more often directly infects the cells in the lungs and people often develop direct viral pneumonia which is a very severe complication and which is something we see much less often than with seasonal influenza viruses.

So I think that one of the important scientific questions and one of the things that we will be monitoring very closely is whether we see changes in the clinical pattern, how this virus causes severe disease in people, and whether they are the same groups of people we are seeing now continue to be at higher risk than other people and whether we continue to see lower rates of infection in older people. Now the other important part of this is that in general it is true that older people get infected less often than younger people. This is pretty clear from around the world but what has also become clear is that when older people get infected they turn out to be very vulnerable to infection so they probably have the highest death rates even though they get infected less often. This is a little bit complicated but these are some of the patterns that we are now seeing emerging. To answer your question, I think it is very difficult to say whether we will continue to see these same clinical patterns but it would be surprising to see them change abruptly very quickly but we will monitor. Thank you.

G. Hartl: We are coming back and Dr Fukuda who is going to clarify one point and then we will go to the next question.

Dr Fukuda: I am sorry, if I miss-spoke, it was just pointed out to me that when we are talking about pandemic H1N1 viruses, these viruses cause viral pneumonia more often than seasonal viruses. I think I may have said that backwards, but the pandemic influenza viruses which cause viral pneumonia much more often, and this is one of the crucial differences between this pandemic virus and the other seasonal viruses that we have seen. Thank you.

G. Hartl: Thank you Dr Fukuda. So now to the next question, Jonathan Lynn from Reuters, go ahead please.

Jonathan Lynn: Hello, am trying to save my question. This is about the stocks of the H1N1 pandemic vaccines that are already there. I know you already touched on this. But could you
clarify whether it's both governments and manufacturers who can really use those existing stocks for the new seasonal vaccine or not?

**Dr Fukuda:** this is a very important question. When we look at the monovalent pandemic vaccine, which has been made, some of these have already been put in syringes and in vials. And those vaccines, the vaccines which are put in those kinds of forms, will not be re-used, or cannot be re-used. However, manufacturers are also making the H1N1 vaccines component, and so this vaccine in that form can potentially be used for the vaccine for the upcoming year. And so I think it is important to know that there is a difference of whether these vaccines have already been put into final form, in which case they would not be possible to put them into next year's vaccines. Whether they are still being manufactured in large bulk form, in which case they would be theoretically possible to put them back into vaccine for the coming year. So it depends on what kind of form we are talking about. Thank you.

**G. Hartl:** Thank you very much. So one last reminder to any journalist who would like to ask a question, please dial 01 and before that, we will go over to Robert Lowes, from MedScape Medical News. Please go ahead.

**Robert Lowes:** Hello Dr. Fukuda, thank you for taking my call. I have two questions.

One, I want to clarify something. I understand that this WHO advisory group is not specifically recommending that these viruses strains or three virus strains should go into a trivalent vaccine. Is that correct that you are not recommending a trivalent vaccine which includes the pandemic H1N1?

And second, if that is the case, is it a good idea for countries to adopt a trivalent vaccine with this pandemic virus. Would that be a good idea? Thank you.

**Dr Fukuda:** Sure. Okay, good question.

Let me provide this clarification. Yes, at this consultation here, we do not ask the advisers to advise on whether there should be monovalent vaccine or whether there should be trivalent vaccine. What we asked them to do is that based on the available scientific information, what viruses should be covered in influenza vaccine. And then in essence, there is a two-step process. After these recommendations are made, there are additional discussions which take place with advisory groups often to the national regulatory authorities or regional regulatory authorities, discussing whether they should have a trivalent vaccine or whether they should have a monovalent vaccine and so on. So again, there really is a multiple step process with different groups giving their input on different type of questions.

As to whether trivalent vaccine makes sense, I think that, yes, for many countries, I think that the answer is that a trivalent vaccine would make sense. There are countries which use a lot of seasonal influenza vaccine. And the seasonal influenza vaccine containing the pandemic influenza virus plus the H3 and the B virus could be very useful, and people would just vaccinated per routine. There are other countries for which other formulations may make more sense or a combination or formulation may make sense. So I think these discussions have to be decided more at the national level. Thank you.
G. Hartl: Dr Fukuda, thank you very much. And to you listening, that's been our virtual press briefing today, 18 February, and one last reminder, the audio file from this virtual press briefing will be up on the WHO website, at www.who.int, and it will be up there shortly. There will be a transcript up later in the day, and just to let you know that next week, our virtual press briefing by Dr Fukuda, will happen on the Wednesday, not Thursday, so that will be Wednesday, at 11 o'clock in the morning Geneva time, 24 February. Thank you very much until next week. Good bye!