



**Transcript of virtual press conference with
Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases,
and Dr Marie-Paule Kieny, Director of the Initiative for Vaccine
Research, World Health Organization
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Gregory Hartl: Welcome to WHO's daily 17:00 o'clock press briefing. My name is Gregory Hartl, I am the Spokesperson for WHO and next to me is Dr Marie-Paule Kieny, the Director of the Initiative for Vaccine Research in WHO, who will be giving you a technical briefing on vaccine development. I would just quickly like to summarize the latest figures we have as of 16:00 Geneva time. We have cases confirmed in 23 countries that are officially reporting 1658 laboratory-confirmed cases of influenza A(H1N1) infection including 30 deaths. Mexico continues to have reported the largest number: 946 confirmed cases; increases have also occurred since last time we reported in: Canada, France, Guatemala, New Zealand, Spain, Sweden and United Kingdom. We can give you more exact figures afterwards if you wish, but now I will hand over to Dr Marie-Paule Kieny.

Dr Marie-Paule Kieny: Again, it's a pleasure to have the opportunity to brief you where the situation with the development of influenza A(H1N1) vaccine and also about the activities that WHO is conducting in this area. As per the figures we have provided last week, as you know we announced that the current capacity to make seasonal vaccine is around 900 million doses per year, and therefore, our conservative estimate is that this would translate between at least one to two billion doses of H1N1 pandemic vaccine, if it should be a pandemic.

For the time being, there seems to be confusion; we have maybe communicated two figures. Sometimes you can see us saying that it will take 4–6 months between identification of a virus and availability of first vaccine lot, sometimes we say 4–6 and sometimes 5–6. The reality is that 4 months would be for those manufacturers who can start immediately, who have been able to start immediate production, like the ones working with the wild type, who do not need to have a virus vaccine strain – which would have been made for this purpose – and who can start working as soon as they receive the wild type strain. For these vaccine manufacturers, it might be 4 months, for the others it likely to be more 5–6 months, and this is the vast majority of vaccine manufacturers.

About some discussion whether you would need one or two shots of vaccine to be protected against infection with H1N1, it is not know at all for the time being. Usually for seasonal vaccination, you are using only one administration of vaccine, although for small children, sometimes you use two doses. For H5N1 – avian influenza vaccine – it has been shown that you need two doses. For this new vaccine, nobody knows. It may be the case that the population has already some experience, some "priming" as we say, and has already encountered the H1N1 [unintelligible] – not the new one – but the human H1N1 seasonal strain, and because of that there is already some background level of immunity. If this is the case, it may be that one dose will be sufficient. But this still needs to be demonstrated, and

it is only in clinical trials in humans with the first doses of vaccine available, that this will be completely clear.

Therefore, we will still need a few months to know whether we will need one or two doses. In terms of proceeding, as you know, the first step after isolation of the virus is to make what is called sometimes "seed strains" or "vaccine strains", "vaccine viruses". This is the starting biological material for the manufacturers. Efforts are still going on in the WHO Collaborating Centres, at the CDC and elsewhere, to generate these strains for the manufacturers and we still expect that these would be available to the manufacturers most likely during the second half of May. We will post on our web site, as soon as the date is for sure, as well as a list of laboratories from which these seed strains will be available and the date, and this as soon as possible.

We have communicated with all manufacturers already, and have assured them and taken all steps to ensure that these seed strains will be available to all of them who so request to the WHO Collaborating Centres.

While this is going on with the preparation for the manufacturing, what have we been doing in WHO? We have been discussing with the manufacturers – as a group – we have had a teleconference organised by one of the association of manufacturers, the IFPMA, where they have invited not only their members but also all the other manufacturers that are not part of the IFPMA but also making the influenza vaccines. This was held on Monday, and we have discussed all the issues that they wanted to know about: recommendations from WHO, seed strains, reagents... We have been informing all of them on the process and on the progress of the preparation.

We have been setting up an Advisory Committee that will provide policy recommendation to WHO on the use of this vaccine.

We are organizing, as I speak, a meeting that has been called by the Director-General in Geneva on 19 May with the heads of all the companies making influenza vaccines. The meeting will be convened by the Director-General and the UN Secretary General who want together talk to the manufacturers, and to discuss with them avenues to ensure more equitable access for developing countries of this vaccine when it will be available.

This will be a high level discussion with the manufacturers, appealing to corporate responsibility and to working together towards the increase of equitable access.

In the meantime, we have already started discussing with individual manufacturers about potential procurement by the UN agencies; for the UN, there are two agencies that actually buy vaccines for developing countries: one is UNICEF and the other one is in the Americas, the PAHO Revolving Fund. We are discussing with the manufacturers how and under which conditions they could allow the UN Procuring Agency, through WHO, to have vaccines as they come out of the production line. This is real time production for the benefit of developing countries.

I must say that the manufacturers that we have had discussions with, have been very forthcoming and we hope that we will be able in a few days – maximum weeks – to announce that some agreement has been signed.

The last area I would like to address before taking questions is whether WHO has already made recommendations, or will WHO make recommendations on switching from making seasonal vaccine to making the influenza A(H1N1) vaccine. What we have recommended for the time being, at present, is a technical recommendation to all manufacturers: to put everything in place to be able to start manufacturing vaccines.

We will have a quite large virtual meeting, with the first circle being the Advisory Committee itself, but then the second circle, being the manufacturers and the regulators to

provide input to the discussion; and then we will have a third virtual meeting of this group on 14 May.

This group will be asked to provide advice to WHO on whether there is enough evidence to recommend, after the 14 May, that manufacturers should start to go large scale manufacturing influenza A(H1N1) vaccine. This is not a decision that the WHO Secretariat will need to take. We need to have advice of the best experts and to have a solid evidence to make this recommendation. We hope that this will be available for them – the evidence – to discuss and make a recommendation that will go to the Director-General, and based on this recommendation from the group, the Director-General may make a recommendation to the manufacturers to start full scale manufacturing. For the time being, we are watching the situation; this recommendation has not yet been made.

As to stop potentially seasonal vaccine production, again there is still evidence lacking to make such a big move into saying if we need or we don't need much less seasonal vaccine for the next epidemic season. We are currently collecting with the manufacturers all data and all evidence on availability of enough material to make seasonal vaccine now. Potentially a recommendation towards stopping production of seasonal vaccine may come in a few weeks, if it does. This is not a done deal; we separate recommendations on starting the initial steps: preparation, pilot lot, clinical trial. This recommendation is already out. The next recommendation might be, following advice from this group, whether to start a full scale production and a further recommendation might be again following review of other available evidence potentially to stop seasonal vaccine, but this is not out yet. With this, I will be very happy to respond to all the questions that I might be competent to address.

Helen Branswell: Two questions please, one is a clarification, Dr Kieny, I think in your opening remarks you said that there is capacity globally to make 900 million doses of seasonal vaccine. In your last press conference you said 700 million: I am wondering if you could clarify that. And the next question I would ask is about the discussions with the manufacturers to make available vaccines as it is coming off the production line, so immediately, for the developing countries, not forcing them to wait until later. In essence that would probably require vaccine manufacturers to vitiate or renege on contracts they have with countries such as Canada and others, for first round of pandemic vaccines in a pandemic. What are you going to say to them? They could be sued as a consequence of that.

Dr Marie-Paule Kieny: About the figures: as I am sure you realize it is very difficult to have a full knowledge of exactly how many because it depends what you take into consideration. So I had said 700 you are absolutely true, I have myself gone back to a study that was published by the consultant Oliver Wyman earlier this year in agreement with IFP manufacturers –WHO has collaborated with that also – and in the graph you can see that you are around 900 million. But between 700, 900, you know it depends what you count. In addition this is perpetually in evolution because plans are being built in a number of countries, they are being validated so there is an increase, a monthly increase if you wish, incremental increase of a capacity. So I had said 700 million that might have been the data by early 2009, it might now be 900 million.

In terms of real time access, yes, this is what we are trying to sort out with the manufacturers. We are well aware, and they are not hiding the fact that they have agreements with a number of governments to provide access to vaccine. Most of the time, the contract will say a number of doses per week or per month. We are discussing with the manufacturers where they are in terms of filling up their books. And to make sure that in what is still remaining as available, that we would have access not to vaccines in six months, but some vaccines will be accessible already in the early weeks, and months of the

production. Of course the availability will be dependent on the manufacturers, dependent on the type of the agreement that they have with countries already, but we know and we have discussed with the manufacturers and most of them at least still have some window of opportunity in their orders. We want to make sure that we do not wait until this window has completely closed, and this is why we are taking a step now already before even having had a recommendation to go full scale to try to ensure access for developing countries.

Eva Ussi, Grupo Radio Centro, Mexico: I would like to ask you two questions if I may. Firstly, the influenza virus has already caused international hostilities particularly against Mexico, who have seen how Argentina, Cuba, Ecuador and China have cancelled flights to and from this country. China went even further and kept Mexican businessmen and Mexican tourists, around 70 people, secluded in a hotel. They were not infected, nevertheless they could only return to Mexico in a special flight. Mexicans feel hurt because they were laterally stigmatized for being Mexicans. This treatment was not given for the United States or Canada. This attitude actually contradicts the recommendations of the WHO, doesn't it? Second question: I would like to know how do you expect possibilities of a mutation; that the virus mutates in a new virus. In this case when the vaccine is available, will it still be effective?

Dr Marie-Paule Kieny: I will let Gregory Hartl respond the question about the IHR and the discrimination. I would not be sure to use the right words, so Gregory up to you and I will take the second question.

Gregory Hartl: We would just say that under the International Health Regulations, which is the legal framework under which the WHO and its Member States are responding to the crises, countries can take additional measures, other, than those recommended by WHO that they feel might be necessary to respond to a public health risk. However, countries adopting measures that are significantly different and/or interfere with international traffic must provide WHO the public health rationale and relevant scientific information for those measures. We have begun the process of getting more information from a number of countries. WHO has not singled out any one country, but has requested information from a number of countries about the public health rationale of their actions. This information will be circulated among IHR Member Countries who may, if they wish, consult with each other on those measures. We do remind you that the IHR does require that Member Countries treat travellers with respect for their human rights, dignity and fundamental freedoms. Nonetheless, screening of travellers, or other activities, as long as it meets these requirements can be considered as consistent and good public health practices, as required or recommended by WHO to prevent or mitigate a pandemic. The key is that they are carried out in line with or respect for human rights dignity, and fundamental freedoms.

Dr Marie-Paule Kieny: On mutation, of course as you know, influenza viruses mutate. So this is why we need to adapt the vaccines all the time. Before this press conference, I went back to the group responsible for the following up on virology with the WHO Collaborating Centres and it is still the case: the virus that is still circulating is similar with what was isolated first. For the time being we have no sign, that vaccine that would be developed using the strain first identified would not be effective. In terms of what will happen in the future is really difficult to predict. At one time it will drift, but it may drift next year, it may drift a lot, it may drift only a little. We do hope that the vaccine that will be made will still be effective as you know even against drifted viruses usually vaccines still have a reasonable effectiveness although it can vary, of course, if the virus is very much drifted. And we hope also that at least with the formulation of vaccine that has been developed using adjuvant, it seems that there is a better ability of these vaccines to induce protection against even drifted viruses. This is something that will be followed as the situation evolves. We are very early in the epidemic as you know, should there be a change in the

recommendation of strain, we will of course announce it as soon as possible, but for the time being everything seems to indicate that the viruses that are being used right now to make seed strains are the right viruses.

Deborah Berling, Global: How many manufacturers have manifested interest in producing these vaccine. Are they mostly from Europe, the United States? Will most of these vaccines be patented? I have heard that there is another traditional way of producing the vaccines, a non patented way? Can you just develop a little bit more on that and how besides UN agencies, who is buying these vaccines, what are the other options for making this vaccine more available to the developing world.

Dr Marie-Paule Kieny: So how many manufactures? Well you have multinationals of course, you know we are always mentioning there are four very large multinationals who are making quite a lot of seasonal vaccines which is used in the world, but there are quite a number of other manufacturers. And we are discussing with all of them. For example in China there is a consortium of manufactures making influenza vaccines, four of them public manufacturers, there are also a couple of private manufactures, there are manufacturers in Hungary, in Serbia, and so we are discussing with all of them, because although they do not have the same individual capacity as a multinational, when you pull all these capacity together, you end up having quite a number of hundreds of millions of doses. We are working with them very much to see how we can help them also, help also the regulatory agencies in these countries to be able to license these vaccines on an emergency procedure. We are working with all of them, and we hope to be able to help them really contribute to the global amount of vaccines for availability to developing countries also.

Now in terms of intellectual property rights and on patents, the general technology to make influenza vaccine is very old. You know the technology you take an egg, you put a virus in, you let it grow, you harvest, you treat, you formulate... This is an old technology, there is no patent on the general way to make influenza vaccine. There are some subtleties, and interesting subtlety that is patented; so certain adjuvants are patented, certain others are not. Some adjuvants, even the well-considered adjuvants, oiling water adjuvant for some of those there are patents which are valid in the US for example, but this product would be free of rights everywhere else. So it is really a question of identifying where patent issues may pose a problem and where they will not. As I repeat, for the general technology, to make influenza vaccine this is patent-free.

About the seed strains or the vaccine viruses if you wish, as you know we discussed already: there are two ways of making the seed strains to make production of influenza vaccine using classical method. Either you do it using a technology called “reverse genetics” – this is patented by MedImmune – or you do it using reassortment. Reassortment is free of patent. For H5 it was not possible to make reassortment because the virus was an avian virus and was killing the egg. Now with this virus now, H1N1, which is not an avian virus, it is possible to make reassortment. Collaborating centres are making seed strains using reassortment and the manufacturers who do not have agreements with MedImmune will be able to use a seed strain that is free of patent rights.

In addition WHO has negotiated with owners of live-attenuated vaccine technology rights access to one of the two live-attenuated vaccine technology, which is available in the world, and we have sub-licenses ready for any manufacturer who is interested. We are currently discussing with a few manufacturers who are interested by this technology and we will be providing them full access to this technology as soon as possible for those who are interested. To sum up, there are patent issues for very specific applications or very specific areas of this manufacturing of influenza vaccine, and pandemic influenza vaccine

production, but for the whole bulk, if you wish, of the aspects of production, this is completely free of IP rights.

Kanako, Japanese newspaper: Could you explain more about how the vaccine should be allocated to many countries once it is finally produced. And who pays? I am just wondering whether it is possible for rich mindful countries can buy lot of those, or not.

Dr Marie-Paule Kieny: You know, most vaccines are made by private companies. So a vaccine is like any other, in certain aspects, is like any other commodity that is produced by a manufacturer, a producer, and which is then marketed and sold to a private or a public customer. Now of course it is not completely like that because as we know there are a lot of issues about public health, about equitable access, and it cannot be considered simply as any other good. For the timing also, it is not known exactly which are the high priority target population in terms of age, in terms of specific health conditions, the people who should have access to the vaccine first. As I am sure you know that for, for example, for seasonal influenza vaccination, it is well-known, for example, that elderly people are one of the prime target for vaccination because for them the severity of the disease is the greatest. For this particular disease we do not know. Is it still the older people who will be most affected, is it the people with underlying health conditions, is it the very young, is it everybody? So first before really going on allocation and recommendation for priority use, we are still not there completely. Of course as soon as the data are available and coming up, in terms of the profile of the population which suffers more of a disease, there will be recommendation by WHO for priority use in certain population.

In terms of countries as I said, we are discussing with manufacturers, they are all aware of their cooperate responsibility, they want to help WHO as much as they can in view of the already existing contractual agreement to provide access to WHO to this vaccine and a further, after we have discussed and tried to secure as much as possible with the manufacturer, the other discussion will have to be placed at the political level between the WHO and governments, to see how this can be played out.

Who pays? Of course there is always a question of money and there is a transaction cost. For the time being the manufacturers that have discussed with us have always either been very open to donation, I can remind you that prior to the H1N1, WHO had had donation from two companies of 50 and 60 million doses of H5N1 vaccine. There are companies that are still considering very well donation to WHO for the benefit of developing countries, and also tier pricing. This is something that is really the norm, I would say, in the distribution of vaccine for poor countries, is that poor countries pay much less their doses of vaccine than the rich countries. Apart from that, who will pay? This again needs to be discussed, it could be donor countries, it could be charity, it could be development banks, and all will be put together to contribute to putting money forward. The first expense will be to buy potentially the vaccine for the ones who have not been donated, but the other one will be to help developing countries bear some of the costs that will be involved in the distribution of these vaccines.

Julian Rush, Channel 4, UK: Two things if I may. One is can you give me some indication of the capacity world wide to make vaccine, whether this means a decision to go for an H1N1 vaccine rather than seasonal vaccine, is it either/or, or whether there is the capacity to do both at the same time? And secondly, what criteria would you use, to make a decision to switch from seasonal flu vaccine to H1N1, given that it means loss of protection against seasonal flu, in order to be able to protect against H1N1 and the corresponding trade off that you have to make there?

Dr Marie-Paule Kieny: In terms of capacity, as we said, as long as we don't have a response to at least three variables. First is the yield: how well will this vaccine virus grow in eggs and how much of the active principle will be coming out; it is very difficult to say exactly what will be the capacity. For example, working with a first viral strain for H5 vaccines, which was a strain coming from Viet Nam, the manufacturer had really difficulties having high yield, and they could only have a third of what is the usual rate. With the Indonesian strain of H5, they could again obtain a yield as high as the one for seasonal influenza. This is virus dependent on a vaccine virus and this the first variable.

The second variable is: what formulation will work; will low dose work; would you need an adjuvant... According to all match of active principles you put in the vaccine dose, then also the capacity may be different.

And the third variable that I want to mention here that will impede on capacity is: how many doses would you need by person. Would you need one dose or two doses. If you need two doses of course you can only vaccinate half the number of people, but we hope that with this virus one dose will be sufficient. Before knowing that for sure, it is very difficult to say how many doses will be available. This is why we have said from the beginning that, being conservative, we think that there will be at least between 1 and 2 billion doses.

In terms of knowing if it possible to continue to make seasonal wild seed while already producing H1, it depends because you can't produce in the same manufacturing plant two influenza vaccines at the same time. This is why manufacturers for seasonal, for example, do the three strains one after the other. Some of the manufacturers have more than one production plant; so these manufacturers in theory could continue to make seasonal in one plant, and have one or more plants already doing the H1N1. It depends on the manufacturer.

In terms of a switch, I have seen somewhere in an interview somebody using me as the spokesperson and saying that "WHO was gambling on vaccine". I do not think we are gambling on vaccines. The decision on switch, as I said in my introduction, is not something that can be taken right now: there are a few factors that need to be taken into consideration in any signal that would say "stop seasonal". And among these factors would be a good knowledge of how much has already been produced. We hope to be able to have that by next week.

Also, about the severity of the disease – of this particular disease – as compared with seasonal vaccine, because you would want to have some seasonal vaccine of course in order to protect the high risk group. I remind you again that seasonal influenza is causing the death of between a quarter and half a million people a year. This is a serious disease, and we need to protect this vulnerable people against this disease. We would not want to have no seasonal influenza vaccine and we think we already have quite a lot of it produced.

These are some of the factors that will be taken into consideration by this policy advisory group when it will work towards making potentially a recommendation to the Director-General that at one point it might be the time to "switch", if you mean "switch" is "stop seasonal". But in the mean time, there may be recommendation coming much before that, could be next week, could be later also, it depends on the opinion of these experts and not on what I would think for example, or what the WHO Secretariat thinks, about starting large scale manufacturing.

David Brown, Washington Post: I have been unable to get from WHO or manufacturers an estimate of the number of doses of a pandemic vaccine that are already claimed under pre-production contracts. I would like to know: do you believe that right now the world deserves to know what fraction of a potential pandemic vaccine manufacturing production capacity is already spoken for and if you do believe that the world deserves to know, how much already has a claim on it, can you give us some estimate?

Dr Marie-Paule Kieny: Currently I do not know with any kind of precision. I hope that we will be able to know, as I said, by next week when we have all the data available from all the manufacturers. The reason why it is difficult to say is that it will depend on the manufacturer. Some manufacturer we know have orders already to coming not to what they can produce but they have orders which are already quite large for these vaccine doses. There are also manufacturers who either have such a large capacity that even with these orders they have a lot of capacity to offer, some others have no pre-purchased doses. It is really a mixed picture. Before jumping ahead and saying how many doses are being locked in contracts, we really need to have more data. There has been one manufacturer who has said publicly, in a teleconference with the other manufacturers, that their company had currently locked into contract enough vaccine to vaccinate a little bit over 200 million people, but this particular manufacturer has a much larger production capacity. Even though we may seem large, this manufacturer still has a lot to offer for other countries. It is not at all that we are hiding anything, I think that the reason why nobody is answering this question is that we don't know.

John Zaracostas: I was wondering and following up on my colleague's question, what assurances do you have on the production capacity, from the industry, the big companies, the independents and the government owned entities. We have not had that clarified by WHO for many months. Secondly, with reference to the antivirals: since they are proving effective, what about the production of antivirals? Do you have any information on that capacity? Or is it also an effective line of defence?

Dr Marie-Paule Kieny: About your second question: I have absolutely no idea. We have colleagues who are following this very closely, I am sure that if there is a press briefing on antivirals, they will be able to update you. I must admit my ignorance personally on what is the capacity for drugs.

How do we know (and I know that this is a question that you keep asking me) that actually what the manufacturers say is the true reality and if they do have this capacity?

First, what we know, is what they deliver on seasonal vaccine. And we know that they have produced for sure around 500 million doses of seasonal vaccine in 2009. So this we know for sure. What we know also is what they have been financed by some governments, including the US government to build its production plants on the US soil which comes over and above of what was existing a few years ago. We have not checked ourselves, but I would trust the US government to be able to check whether their investment in these manufacturing plants have been well invested and indeed whether these plants have been built. Although WHO has absolutely no capacity and no mandate to go and verify production plants (“show that you can make so many doses [unintelligible], if this is the case, or you can have so many eggs/week”)... we really trust what the manufacturers tell us is the real truth. In addition, we know and they know that this is not the time to play games. They have always been very responsible and we do trust that what we say in terms of capacity represents indeed what is currently available.

Vijay, The Economist: Two clarifications, if you don't mind. First, you have mentioned the range of flu deaths per year at 250 to 500 000. We have heard Dr Fukuda earlier this week give the figure of only 500 000. I wonder if you could clarify what is the right number to use, if there is one, or there is uncertainty of how many flu deaths are per year. And the second question, the current manufacturing methods for flu vaccines typically use the egg-based approach, there are those who argue that cell-based approaches may provide a more rapid response. Is it possible that these are ready for prime time, or probably not in time to respond to the current crises.

Dr Marie-Paule Kieny: In terms of flu deaths, in purely epidemiological estimates of the number of any decease, you certainly know that there is a big uncertainty. The surveillance is not that precise, so therefore, you need to take a number of countries and then you do modelling, and then you extrapolate. Therefore, you cannot come with a point estimate and you can say, these many, even with a very high degree of precision, but actually there is always a range.

So why do I say 250 to 500 000, because this is the official numbers that we are using. We know that this is lightly to be underestimated. And why is that? This happens quite often and this is a topic of a lot of studies, especially in high-income countries, influenza is the major cause of deteriorating health in elderly people. You may have people who are quite old, ageing very well and who, because they have influenza one winter, suddenly deteriorate and after that, die of other causes. So how do you consider that? These are not influenza deaths but it is a cause of morbidity and further deaths. In addition, in many settings, flu is a syndrome that can be confused with other syndromes: it is a respiratory disease, when people die of pneumonia – is this an influenza pneumonia or is it strep pneumonia... it is difficult to know. So this is why it is thought currently by most experts that the number of flu deaths is currently underestimated. When we say between 250 to 500 000 – which is our current estimate – we can assume that actually the higher figure may be closer to the reality.

About cell culture, you are absolutely right. Most of the influenza vaccines available and used today are derived from embryonated eggs. There are few manufacturers that have development on cell cultures, very few of these vaccines are currently licensed. There are two or three manufacturers that do have licence product on cell cultures. These ones will be able to go immediately and make cell culture vaccines, but in terms of quantity of vaccines globally, this will represent only a small proportion of the amount of vaccines which will be available in the months to come.

Andy Pollack, New York Times: I have a couple of questions: First: you have mentioned that after meeting next week or soon as next week, there might be a decision on whether they go ahead with large scale manufacturing. I am interested in know what information will be come available between now and then that will lead to a decision NOT to go ahead with large scale manufacturing. The second question to follows-up with cell-based: there are various companies developing new kind of vaccine technology: DNA vaccines, sub-unit vaccines, viral particle vaccines, that they claim could allow for huge production in a relatively short period of time. These have not been approved for use yet. Would there be any circumstances where WHO would encourage or allow such production? Encourage individual country to take a gamble on some of these newer approaches?

Dr Marie-Paule Kieny: What might or might not come out of next week's meeting would be a recommendation that will be given to the Director-General and the Director-General will consider this and either issue or not. Usually she takes great consideration of advice and recommendations from this group. To recommend to manufacturers to produce large scale stocks of influenza A(H1N1) vaccine. The decision is not that of WHO as you know. The decision will be of the manufacturers to take. It is their prerogative to decide what they produce. So what information would be potentially available to say that is not yet the time? Well, it is a question of saying how this infection evolves. There are new data, new evidence coming every day about the epidemiological pattern, about the likely percentage of population who might be affected or at least be infected, about the severity of the disease. All this information as it comes will be taken into consideration by the group as they make their recommendation.

Your last question is about new technologies and this for sure is a question that will come up more and more. What we would like to avoid is to say, does or would WHO recommend countries to take a gamble? Is really difficult to take a gamble to say, we don't know whether it will or not be safe, so let's gamble on safety. I don't think WHO nor any regulatory authority wants to gamble on this. You may remember that there were some difficulties in 1976 with the last scale mass vaccination campaign in the US against an outbreak of swine flu and nobody would like to repeat this experiment.

What about new technologies? They look very, very promising. There is no doubt that in the future (but when?) we will have other vaccine that will not be made in eggs, but we don't know how large the production will be in a small amount of time. The difficulty at this stage is that at the maximum these candidate vaccine have been tested in what is called Phase 1 clinical trials.

This Phase 1 clinical trial is a few doses in healthy adults usually. There is a big leap of faith to say that a few doses in individuals have been vaccinated and that you can take this very same product and inject it in millions of people. This is why for all novel vaccines, fantastic innovations, some of them are really great, but all these innovation need to be tested very thoroughly in clinical trials and the dossiers reviewed by National Regulatory Authorities before authorization to deploy them is given. This is why, to the best of our knowledge, none of these new vaccine is ready for large scale implementation at the present.