



**Transcript of virtual press conference with  
Gregory Hartl, Spokesperson for H1N1, and  
Dr Marie-Paule Kieny, WHO Director of the Initiative for  
Vaccine Research, World Health Organization**

**30 October 2009 (updated 2 November 2009)**

**GREGORY HARTL:** Welcome to the WHO's virtual press briefing. My name is Gregory Hartl. Before we go forward, can I just let you know, please, that from this week forward, we will resume weekly press briefings, they will likely be on Thursdays. But for today, it is on Friday, because as we are reviewing today, the SAGE recommendations on pandemic H1N1 vaccine. The SAGE ended yesterday and we are here with you today.

With us is Dr Marie-Paule Kieny, the director for the initiative on vaccine research at WHO Headquarters, who will let you know about the major conclusions about SAGE concerning pandemic H1N1 vaccines. Other subjects will be addressed in subsequent press briefings, starting next week, likely on Thursday, and that would be with Dr Keiji Fukuda. I will now introduce Dr Kieny, who will make her introductory remarks, and we will open it up for questions. Thank you.

**DR MARIE-PAULE KIENY:** Thank you very much. I would like to update you today, on the outcome of the meeting on SAGE, which was held this week, and of the recommendations that SAGE has provided to WHO.

SAGE have reviewed the policy recommendations that they have given in July, and has considered that the recommendations given were still appropriate, notably on the priority groups for vaccinations, and has provided a few additional recommendations.

The three main recommendations are as follows:

1. First, having reviewed the immune response induced by the licensed pandemic influenza vaccines, SAGE has recommended that one dose of vaccine is suitable for people, from 6 months of age upwards.
2. The second recommendation is that, after having looked at the safety profile of these pandemic influenza vaccines both in clinical trials and in deployment, they have concluded that the safety profile was good, and recommended that pregnant women can be immunized with any of the licensed vaccines.
3. They have looked at the potential for co-administration of seasonal and pandemic influenza vaccines and concluded that these vaccines can be injected simultaneously.

[Note: See [http://www.who.int/csr/disease/swineflu/notes/briefing\\_20091030/en/](http://www.who.int/csr/disease/swineflu/notes/briefing_20091030/en/) for the full recommendations.]

Now, let me give you some background.

SAGE stands for Strategic Advisory Group of Experts. It is the highest level advisory body to WHO on immunization and vaccine matters. SAGE is made of independent experts, selected from all over the world. All the WHO regions are represented, and they are selected for their independence and for their expertise, in all the different topics which are important when you discuss vaccines and immunizations.

Prior to be selected to SAGE, they are requested to declare any conflict of interests, and it is only upon favourable review of these potential conflicts of interests that they are actually selected as SAGE members.

At SAGE meetings, you have other stakeholders who are invited to attend and to listen to the debate. These are the main stakeholders responsible or involved in national and international immunization matters, and they represent non-governmental organizations, other health agencies, national regulatory authorities, national health authorities, as well as the industry. None of these other stakeholders is invited to participate in the policymaking and in formulation of recommendations by SAGE.

SAGE met on the 28<sup>th</sup> of October, this is two days ago, to review the current status and the current evidence related to pandemic influenza, and to pandemic influenza vaccines and immunization. This is the first full SAGE meeting that was held on this matter, since the previous meeting which was held on July 7<sup>th</sup>. As I am sure you appreciate the level of evidence which is available now, in October is much higher than what available in July, and therefore, the recommendation of SAGE at this particular meeting is much more precise than what could be said in July.

So as I said, the first recommendation is about vaccine regimen, about how many doses should be used to vaccinate against pandemic influenza. So SAGE looked at the result of clinical trials, they also looked at the national regulatory authority decisions or recommendations on the use of these vaccines, and have concluded that in view of immune response, reported in vaccinated populations, as well as of public health considerations, that one dose was appropriate to vaccinate individuals from 6 months of age.

So this includes using live attenuated vaccines, using inactivated pandemic influenza vaccine, either non-adjuvanted or adjuvanted, like those manufactures' and marketed by GSK or Novartis. So for all these vaccines, one dose for all populations.

In terms of populations less than six months of age, there is currently no indication for vaccination of these infants, and this continues of course, to be the case. SAGE has also recommended that more studies should be done, including people with immunodeficiency, in clinical trials, in order to assess what could be the best regimen for immunization of these people. So in the meantime of course these persons can be immunized and should be immunized with one dose of vaccine, potentially even with a second dose, because they usually react less well to vaccination but mainly most information is needed, on the immune response, not on safety, safety has been deemed appropriate.

The second important recommendation is about safety and safety of use in pregnant women. So SAGE reviewed the results of clinical trials. Currently, there has been several thousands of persons involved in clinical trials of pandemic vaccines, and also no more than several hundred thousands of people who have been vaccinated in real field operation by deployment of vaccines organized now by 14 countries.

So all the reports received today, following vaccinations either in clinical trials or in mass vaccination campaigns, have shown that the safety profile of these pandemic vaccines is good, and is very similar to the ones which is known for seasonal influenza vaccines. Nothing special in terms of adverse events has been noted. Therefore SAGE has considered that in view of the particular importance to vaccinate pregnant women which are a significant higher risk of severe adverse outcome following infection with a pandemic virus, especially in the second and third trimester of their pregnancy, that these women can be vaccinated with any of the currently licensed vaccines, licensed by a functional regulatory authority, unless this national authority has made them a specific contra-indication for use of any specific product.

The third area where SAGE has made recommendation is about co-administration of seasonal and pandemic vaccine. As you know in certain population, currently, you have two types of administration of influenza vaccine going on. One is with seasonal vaccine, to protect the population against the seasonal strain, which is still circulating in certain areas. And the other one, which is meant to protect them against the pandemic influenza.

So SAGE has looked again at all the data which is existing, and has recommended that in the vast majority of cases, it is safe and indicated that these vaccines be co-administered, which is that, they can be administered simultaneously.

So what is the exception? The exception would be, when both vaccines are of a live-attenuated type, which is the vaccines which are administered not by injection but by nasal spray, and these vaccines should not be co-administered as indicated by national regulatory authorities.

Finally, to conclude, I would like to sum up.

SAGE has recommended that one dose of vaccine can be used for all populations older than six months of age. It has also concluded that pandemic vaccines are safe and can be used in pregnant women. And this applies both to inactivated adjuvanted and non-adjuvanted vaccines, as well as to live attenuated vaccines. And they have also recommended that seasonal and pandemic vaccines can be administered simultaneously.

With this, I would like to end my introduction and will be very happy to respond to your questions.

**GREGORY HARTL:** Dr Kieny, thank you very much. Before we go over to questions, may I remind the listeners that an audio file of Dr Kieny's briefing will be available immediately afterwards, on the WHO web site and a transcript will be available later today. So with that, can we go to the first question?

**HELEN BROWNSWELL, CANADIAN PRESS:** My first question is with regards to recommendations for one dose for everyone 6 months and upward. I think a very few data regarding efficacy of this vaccine, and children as young as 6 months. Is this data based, or is reflection of the fact that it will be best, given that supplies are limited, that the priming children that young, might be useful and might cut disease but you may not prevent disease in those kids.

**DR KIENY:** So you are right that actually the data available from clinical trials in very young children is still limited. Nevertheless, the results which are available indicate that these children do mount an immune response following vaccination with pandemic influenza vaccine. So, as you may

know, SAGE has not recommended universal vaccination, but has recommended that countries consider which groups should be prioritized according to their own needs and conditions.

So the recommendation of SAGE is when children are among the groups that country wants to immunize, it is important to immunize as many children as possible because when they are considered this priority, and therefore, SAGE considered that the first priority in this case when children are targeted should be to immunize as many children as possible with at least one dose.

**HELEN BROWSWELL, CANADIAN PRESS:** OK, if I could ask a follow-up regarding pregnant women. Again, the recommendation is not based on new data per se, is it? Is it based on the fact that the places where it is being adjuvanted H1N1 vaccines is being administered to pregnant women, there has been anything seen that would raise a red flag?

**DR KIENY:** Well this is based on the fact that the safety profile of adjuvanted vaccines and non-adjuvanted vaccines are very similar, and the fact that the non-adjuvanted vaccines have been recommended for pregnant women for many many years. So there is no reason in SAGE view to distinguish between both types of vaccines. In addition, as I am sure you know, inactivated adjuvanted vaccines have been licensed for pregnant women by the corresponding regulatory authority.

**FRANK JORDANS, ASSOCIATED PRESS:** Dr Kieny, I would like ask you about the fact that in some countries, there seem to be two-tier vaccine policies going on. A lot has been said, last week, and in Germany, for example, when it transpired that the government had bought one type of vaccine for senior politicians and soldiers and another type for the general population. Did the SAGE group say anything about the consistency of vaccine administration in a single country, and which of those two vaccines would be better?

**DR KIENY:** Well, the SAGE has not deemed appropriate to make any difference between the vaccines which have been licensed by functional regulatory authorities so far, so there may be many reasons why a country may have ordered different types of vaccines. Would it be only not to be reliant on a single delivery? So we know of many countries who are acquiring more than one type of vaccine. And then you need to take decision on which group you vaccinate with which vaccine. You can say also that adjuvanted vaccines have been shown to induce higher immune response quite often than non-adjuvanted vaccines, and therefore using in certain populations an adjuvanted vaccine which is likely to also confer a broader protection with potentially drifted or mutated strains, may be of the advantage of that population.

**ALINE GOBY, CANADIAN BROADCASTING CORPORATION:** Thank you very much. I understood what you said about the safety of all vaccines adjuvanted or not, but to make it really clear, it is just that we see from the wire from ASP, in Geneva, exactly where you are, Switzerland decided that the adjuvant AS03, used by GSK, is not approved in the vaccine pandemics for pregnant women, children aged 18 and less, and adults of more than 60 years old. And in the US, it's the same thing. The adjuvant vaccine has not been approved. So I suppose you looked when you did your survey into the experience of those countries and their expertise so could expand more on the examination you have done on this question?

**DR KIENY:** well the type of vaccines that get licensed and the indication is of course national prerogative, a need each national regulatory authority sees this in the light of a particular country situation. So, this is why, as you have rightly pointed out, for the same vaccine, different regulatory authorities have made different decisions. The EMEA, in Europe, has licensed these adjuvanted vaccines for use in pregnancy.

These vaccines were not submitted so far for licensing in the US so it is not that the US has not licensed them, they have not considered the license yet. In Switzerland recently, the Swiss authorities took another decision. Again this is in view of their particular situation and it is really in view of trying to sum up and come with a recommendation that could be more global that SAGE has looked at the safety results of this vaccine and compared them with what is known of seasonal vaccine, and has really recommended that in its view there is no reason to favour one vaccine as compared to the other for all these groups and in particular for pregnant women.

**GREGORY HARTL:** Dr Kieny, thank you very much. The next question is from Martin Enserink of Science Magazine. Go ahead please.

**MARTIN ENSERINK:** Hello, and thank you for taking my question. The EMEA last week repeated its statement from September that there is not enough evidence to recommend just one dose, so essentially they seem to be sticking to a two-dose recommendation. So countries now have two different sets of recommendations. I wonder how they should deal with that. And is SAGE saying with this statement that it is [...] not to use a double dose? Is there anything against it, according to SAGE? Is there any reason why countries should not do it?

**DR MARIE-PAULE KIENY:** Well, in terms of, if you look at the statement issued by EMEA you will see that EMEA says that for the time being because they have not had the opportunity to review enough data, in their opinion, that they are still sticking to the recommendation that two doses would be preferable. But when you read the statement a little bit down the line, it also said that the information which is available now to them seems to indicate that for the Novartis and GSK vaccine, one dose seems to be sufficient. So we are waiting to see when and whether of course, but when also the EMEA will change their decision on these particular two vaccines. So in terms of whether a booster would be welcome or not, I would say what SAGE says is that one dose is sufficient. These vaccines are very safe so there is nothing against giving a booster, certainly in terms of safety but also in terms of the scarcity of this vaccine right now. You can also take the other option and say that the second dose could be used to vaccinate another person.

**GREGORY HARTL:** Dr Kieny, thank you very much. The next question is from Jonathan Linn from Reuters. Go ahead please.

**JONATHAN LINN:** I have two questions if possible. I would like to hear your thoughts about the long-term supply of flu vaccines given that so many people are now coming in and producing it, and the price is coming down and there was over-capacity in the sector before which pushed many companies to get out of flu production. Are you worried about a boom-and-bust cycle? Secondly, when you look at the supply problems that you are seeing in the United States, whether you think that the US government has made a mistake by

insisting on the unadjuvanted vaccines when the rest of the world is using adjuvants and getting a lot more bang for their buck at the moment. I have a third one. Ukraine has closed schools apparently and banned all public events today on restricting people's movements round the country after getting their first deaths of swine flu. Would you have any comment on that?

**Dr Marie-Paule Kieny:** So this is a question with many hidden questions actually. I do not pretend that I will be able to respond completely to all of them today so in terms of the flu vaccine market, it is true that the global capacity has increased very substantially from somewhere around 300 million doses of trivalent vaccine to nearly a billion doses right now. So this is clearly a surge capacity in terms of seasonal vaccine update. It is still not enough in terms of capacity to make a pandemic vaccine when pandemic vaccine is needed, which is as you know every number of decades. So how the situation will evolve after the pandemic is over still is an unknown but certainly we will see a push to try and maintain this capacity by having more countries take on seasonal vaccination for their population, at least for the people who are at highest risk for severe outcomes with seasonal flu, and also we will be seeing in the coming years some new technologies coming on the market and with these new technologies it is likely that the surge capacity, which is the capacity to produce more vaccine when needed, when you have a pandemic will be better than what we have currently with vaccines produced on eggs where surge capacity is limited.

Now, in terms of availability of vaccine where the US has chosen for the time being to use non-adjuvanted but also live attenuated vaccine, which has a lot of advantages in terms of number of doses that you can make by eggs. This is a situation which may evolve as the US national authority will review more requests for marketing authorization of adjuvanted products, and we will see in the coming years how this will result. So, finally about Ukraine. There is and there has been a statement by WHO that in certain circumstances closure of schools may have a positive effect in reducing the speed of transmission of the virus and it is indeed a national prerogative to decide whether in these particular circumstances right now of the epidemic in the country it is indeed appropriate to close schools as has been done by many other countries before.

**GREGORY HARTL:** Dr Kieny, thank you very much. Next question is from Richard Knox of NPR. Richard, go ahead.

**RICHARD KNOX:** I just want to be very clear of what you are saying about the number of doses needed in children under 10. Are you saying that the SAGE Committee believes that one dose of unadjuvanted vaccine is sufficient even in children under 10, and so therefore children of that age who have already received one, do not need a second? And secondly, what do the data say, as limited as they are, on the immunogenicity of one dose of vaccine in these younger children? Do they appear to be equivalent [...] or less than equivalent?

**DR MARIE-PAULE KIENY:** So, as you rightly point out for the time being, the data which are available are not very many, and the SAGE recommendation could change as more data is coming in. Nevertheless, what is known is that all these vaccines do induce a response which is a significant response in all ages of children. Do they all induce the same high level of response? No. Some induce a slightly lower immune response. Nevertheless in view of the fact that for the time being for the countries who want to carry out a very large vaccination campaign in children, some of the countries may encounter some rarity: the

number of the vaccine doses that they have made may not be sufficient to provide two doses to all the children. This is why in terms of public health, SAGE has recommended for the time being that in those countries where children are on the priority list for receiving vaccines among the first group, which is not the case in all countries, priority should be given to all of them, or as many of them, one dose rather than vaccinate only half the same number of children with two doses.

**RICHARD KNOX:** Dr Kiemy, the group is not seeing any difference between adjuvanted and non-adjuvanted vaccines in terms of immunogenicity in these young children. Is that right?

**Dr Marie-Paule Kiemy:** It certainly seems that adjuvanted vaccines induce a high immune response but in general there is not enough data available to make a general statement.

**Gregory Hartl:** Thank you very much. The next question is from Deutsche Presse [...] go ahead please.

**DEUTSCHE PRESSE:** I am confused about the age that you recommend. In your press statement today you say that SAGE recommends to give immunization to children above the age of 10 and you say that between 6 months and 10 years the data is limited. Now you just said on the phone that you recommend from the age of six. So, which is it: 6 months or 10 years?

**DR MARIE-PAULE KIENY:** You are right that actually there are two pages if you wish, or two lines in the SAGE recommendations. One concerns adults as well as adolescents. This means people starting from the age of 10. So 10 years of age and older where the data that SAGE has indicated sufficient to give them one dose. In children between six months and 10 years of age, the amount of data is less and therefore the current SAGE recommendation is that in case these children are in the priority groups, the priority should be to give them at least one dose of vaccine now and to cover as many of them as possible, provided that they are in the priority group.

**GREGORY HARTL:** Thank you very much. Next question is from Paul Ban ki Moon of Le Monde.

**PAUL BAN KI MOON:** My first question is can you give us an update of the availability of doses for developing countries to the present, and how the efforts of WHO to get those countries not forgotten have succeeded. Second, if developing countries stick to this one-dose only immunization, how do you foresee the discussions to have more doses given or sold to developing countries?

**DR MARIE-PAULE KIENY:** The WHO initiative to provide access to pandemic vaccine for developing countries is getting into an operational phase, I may say. We have, as of today, secured 156 million doses and we are looking forward to reach 200 million doses that we think will be needed to ensure that the 95 countries which have been currently been put on eligibility list that will receive vaccines donated by WHO would be able to cover at

least 10% of their population. So, vaccine has been donated to WHO both by four manufactures as well as by governments who had acquired vaccines before. I must also that in addition to donating vaccines, some governments of countries are also donating syringes and needles and similar equipment as well as finances to assist with the deployment of the vaccine. The Director-General has approved the list of countries. These are developing countries all over the world. We have the first list of countries who are being contacted right now, at least 16 countries who will be the first countries to receive vaccine out of this donation and we expect that we will be able to provide vaccines to these countries up to the level of 2% of their population first during either at the end of November, or the first half of December. We are finalising all the contracts with the donors and with the donor companies and governments and hope that this delivery schedule will be possible. In line with the SAGE recommendations these developing countries are expected to immunize as a first priority the health care workers with this vaccine.

**GREGORY HARTL:** Dr Kieny, thank you very much. We will take two more questions. Next one is from Mr [...] Poleliman. Go ahead please.

**MR [...] POLELIMAN:** My name is [...]. There are indeed different immunization strategies around the world, different countries in regard to adjuvanted and nonadjuvanted vaccines and they are causing much confusion in the population. Are you worried that these different strategies will affect total immunization achieved around the world and do you see if these decisions are in fact based on science or are they based more on psychology?

**DR MARIE-PAULE KIENY:** There is certainly a lot of disinformation around about vaccines, about safety, about regimen and I can only encourage everybody and you, who are responsible and whose main function is to advise and to inform the public, to look at our website. We keep it up to date and you will find the latest information on safety and the latest recommendations on WHO. We are aware of the confusion that some statements can cause and we will try as much as possible to provide accurate information to the public and to yourselves.

**GREGORY HARTL:** Dr Kieny, thank you. The last question is from CNN. Go ahead please.

**CNN:** I am going to yield to the next person.

**GREGORY HARTL:** Do we have one more question? If not, I would like to say thank you very much for today. This has been the virtual press briefing from WHO Headquarters with Dr Marie-Paule Kieny, the Director for the initiative of vaccine research.

Can I remind you please that there will be an audio file going out very shortly on the web site, and later today a transcript of this briefing. The web site is [www.who.int](http://www.who.int). The next virtual press briefing should be next Thursday. Thank you to everyone. Good day.