Gezondheidsraad **President**
Health Council of the Netherlands

To the Minister of Health, Welfare and Sport

Subject	: Vaccination against pandemic influenza A/H1N1 2009: target groups and prioritization (3)	
Your reference	: PG/CI-2.966.756	
Our reference	: 337/KG/mj/824-N	Publication no. 2009/16E
Enclosure(s)	: 1	
Date	: November 9, 2009	

Dear Minister,

On 17 August and 17 September 2009, the Health Council of the Netherlands and the National Institute of Public Health and the Environment /Centre for Infectious Disease Control Netherlands (CIb) presented joint advisory reports on the target groups and the prioritisation of vaccination against pandemic influenza A/H1N1 2009.[1,2] These organisations are jointly monitoring developments at national and international level, offering advice where needed. A panel of experts met again on 4 November 2009. On that occasion, they also addressed the supplementary request for advice that you submitted on 29 October 2009. Here we present the conclusions that they reached in the course of their deliberations, together with answers to your questions.

What is the experts' assessment of the current epidemiological situation, and of the possibility of adverse changes in the virus?

The picture emerging from recent international epidemiological data is unchanged from the one that was presented in the advisory report of 17 September 2009.[2] In general, the clinical picture is similar to that of seasonal flu. The vast majority of patients experience no complications and go on to make a full recovery. Serious illness and mortality are still rare, and mainly occur among people with pre-existing, underlying disease. One point of difference with seasonal flu, however, is that influenza A/H1N1 2009 occurs more commonly in children and young adults. The data currently being reported by southern hemisphere countries like Australia and New Zealand is of particular interest in this regard. These countries have effective surveillance systems. Data on their first flu season involving influenza A/H1N1 2009 may well be indicative for the present flu season in the northern hemisphere. The 2009 influenza season in Australia and New Zealand was relatively short, which has limited the magnitude of the disease burden involved. Mortality from influenza has been limited, but the disease has imposed a heavy burden of care, especially upon intensive care units.[3-5]

P.O. Box 16052
NL-2500 BB The Hague
Telephone +31 (70) 340 66 25
Telefax +31 (70) 340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 VX The Hague
The Netherlands
www.gr.nl

Gezondheidsraad **President**
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In previous advisory reports, the experts stressed that it is difficult to predict how the pandemic will develop.[1,2] It is important to note that, to date, there have been no reports of mutations that boost the pathogenicity of the virus.

In the Netherlands, there has been a significant increase in the spread of influenza A/H1N1 2009 in recent weeks, as reflected in the number of patients with influenza A/H1N1 2009 who have been admitted to hospital.[6] Meanwhile, the vaccination campaign targeting high-risk groups and health service personnel is in full swing. Although the influenza season started earlier than usual this year, experts expect that the vaccination campaign will still have a major positive impact on the ultimate burden of disease.

Since the presentation of your advisory report on 17 September, has there been any new information regarding the development of viral resistance to antiviral drugs?

To date, there have only been small-scale occurrences of resistance to anti-viral drugs by influenza A/H1N1 2009. On 22 October 2009, the World Health Organization reported 39 cases of resistance to the antiviral drug oseltamivir.[7] These reports came from geographically separate locations and were unconnected to one another. As yet, there have been no reports to indicate that oseltamivir-resistant influenza A/H1N1 2009 is spreading. One case was reported in the Netherlands, but here too there was no further spread of resistance. It is important to continue to study the spread of resistant viral strains, especially as the growing use of anti-viral drugs (triggered by the rising number of cases) increases the risk that resistance will develop.

With regard to the growing use of antiviral drugs, the experts would like to draw attention to the following points. They emphasise the importance of making proper use of antiviral drugs in the treatment of cases. The CIb has already identified those groups of patients who are eligible for treatment with antiviral drugs[8], and the experts stress the importance of following this guideline. As also stated in the CIb report, the experts advise against the prophylactic use of antiviral drugs, as this is not only of limited use but it also favours the development of resistance. Finally, it appears that - in critically ill patients - antiviral drugs can still have a beneficial effect more than 48 hours after the appearance of the first symptoms. Accordingly, the experts strongly advise that the period of treatment be extended where necessary.

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

Gezondheidsraad **President**
Health Council of the Netherlands

Since the presentation of your advisory report on 17 September, have there been any new insights regarding the possible expansion of medical high-risk groups to include certain age-groups such as young people?

The previous advisory report indicated that, in other countries, influenza A/H1N1 2009 affects relatively more children and adolescents than does seasonal flu.[2] That view was recently confirmed by publications on the course of the epidemic in Australia and New Zealand, and in the American state of California.[3,9] There is no evidence of increased mortality in these groups. However, illness caused by influenza A/H1N1 2009 not only led to the more frequent hospitalisation of young people in general[9], but also to larger numbers of children being admitted to paediatric intensive care units or PICUs.[3]

In recent weeks there has been a substantial increase in the number of patients admitted to hospitals in the Netherlands with influenza A/H1N1 2009.[6] Here, too, general practitioners and paediatricians are seeing more sick children below the age of five than would be the case with seasonal flu. In addition, relatively large numbers of children in this age group are being admitted to hospital. Children below the age of five have a higher risk of complications (such as pneumonia) and severe secondary bacterial infections. One reason for this is that the immune systems of very young children are still immature, another is that young children have had no previous contact with these viruses and bacteria. Although the risk of admission to hospital and intensive care is greater in children with a pre-existing, underlying disease, a substantial number of young children who were previously healthy are also being admitted. No precise data is available concerning either the period of admission or the severity of the symptoms, but paediatricians indicate that there has been a substantial rise in the numbers of seriously ill young children in hospitals.

Paediatricians report that the increasing number of sick children in the Netherlands will lead to a situation in which the country's PICUs are running at full capacity. The experts set out a scenario in which (as a result of this exceptional situation) problems may develop regarding the availability (and, consequently, the quality) of care if there is any further increase in the number of sick young children. This increase could be boosted still further by infections with respiratory syncytial virus, which mainly occur in children under one year of age. In a recently published report, the Netherlands Health Care Inspectorate stated that, while the PICUs theoretically have

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

sufficient capacity, in recent years there have been times when no more beds were available.[10] These moments coincided with the peak load caused by respiratory syncytial virus infections.

Experts stress the importance of vaccinating the high-risk groups defined in previous advisory reports, including children with a medical risk factor associated with influenza. In addition to countering serious illness and possible death (for which these groups have a significantly higher risk), this vaccination also prevents PICUs and intensive care units from becoming overloaded. Overloads like this can lead to additional mortality, also among patients suffering from diseases other than influenza A/H1N1 2009. In this context, the experts would like to emphasise a point made in their previous advisory report. This concerns the importance of vaccinating any health personnel who may have direct contact with patients in the previously defined high-risk groups.

When the panel of experts met on 4 November 2009, there were extensive discussions concerning possible additional measures aimed at limiting the burden of disease. One of the challenges faced during the meeting was the limited availability of scientific data. Furthermore, time is of the essence. The number of cases in the Netherlands is increasing, it takes time to put any decision into effect, and vaccination does not provide instant protection. The point at which it will no longer be possible to implement a recommendation concerning the vaccination of extra groups is rapidly approaching.

Based on current data, the experts have made the additional recommendation that all children up to the age of four should be protected against influenza A/H1N1 2009. The primary purpose of this protection is to counter or curb both a substantial burden of disease among young children and a serious disease course that requires hospitalisation. A secondary goal involves the implications for admissions to the PICUs. The reason for this is that if the over-representation of young children in hospitals has the knock-on effect of increasing admission to PICUs (as has happened in other countries[3]), the experts expect severe capacity problems. These issues too can be alleviated by protecting healthy children up to the age of four against influenza A/H1N1 2009. This protection can be achieved as follows.

Experts recommend that children from six months to four years of age be vaccinated against influenza A/H1N1 2009. The safety data that is currently available, although limited, gives no cause for concern. Furthermore, the experts consider it likely that the efficacy and safety data for other age groups will also apply to young children. With regard to the vaccination of this group of young children, the experts recommend that priority be given to the vaccination of children from

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

six months to two years of age. This is due to the relatively large proportion of hospital admissions involving children in this age group. The precise dosage to be used when vaccinating children will have to be determined in further consultation with the European medicinal product authorities. In most cases, half a dose may be sufficient.

It is not possible to vaccinate children below the age of six months, as the vaccines have not been registered for this age group. For this reason, the experts recommend vaccination for those sharing a house with babies of up to five months of age. This will reduce the risk that the very youngest children will be exposed to the virus.

The experts have not recommended that older children outside the previously defined high-risk groups be vaccinated. This is because the data and experience gained to date indicate that they have a lower incidence of disease than those in the youngest age group.

Is there any new information regarding the number of doses needed for full protection?

The advisory report of 17 September 2009 contained details of the initial results of studies involving the administration of just a single dose instead of the two doses that are presently prescribed.[11,12] The experts recommended that the current system of two doses of vaccine be maintained. That view was based on a number of considerations. Firstly, the vaccines in question were not the same as those being used in the Netherlands. Furthermore, the study only involved small groups of healthy adults between the ages of 18 and 60, none of whom were members of high-risk groups. Furthermore, the possibility cannot be excluded that these preliminary results may, to some extent, have been influenced by the use of an overly sensitive technique or by previous contacts between the study's subjects and influenza A/H1N1 2009 or a related virus.

The experts have since had access to preliminary, unpublished data pertaining to the vaccines that are being used in the Netherlands. However, there are also some reservations with regard to the results of the studies into these vaccines. Here too, the studies mainly involved healthy adults between the ages of 18 and 60. As with the previously reported studies, the subjects' response to an initial dose of vaccine was assessed by serological testing, which raises questions concerning the interpretation of the results. With respect to these technical questions (which have previously been expressed), studies are being conducted in approved reference laboratories, but no results are expected in the near future. For this reason, the European registration authorities do not feel that

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

this data provides sufficient grounds for them to modify the dosage recommendation. The experts have also had access to initial, unpublished data on the effects, in healthy children, of a single dose of the vaccines that are being used in the Netherlands. Here too, there are doubts concerning the interpretation of the data.

With regard to vaccination, the experts conclude that it should have the greatest possible efficacy. They also maintain that the dosage recommendations of the European registration authorities (a vaccination schedule consisting of two doses) should be followed. This is particularly applicable to those who, on the basis of on an existing medical condition, are members of a high risk group for influenza. Many individuals in these groups have relatively inactive immune systems, which means that results obtained in healthy adults cannot simply be extrapolated to their situation.

Is there any new information regarding the risk to healthy pregnant women and the implications of vaccinating this group?

Pregnant women who, on the basis of an existing medical condition, are in a high risk group for influenza, should (as previously recommended) be vaccinated against influenza A/H1N1 after the first trimester of their pregnancy.[1] On the basis of the initial data, it was not possible to accurately assess the extent to which pregnancies as such (i.e. where no medical risk factor was involved) might be at increased risk of complications as a result of influenza A/H1N1 2009. The advisory report of 17 September 2009 stated that data from several countries suggest that even healthy pregnant women can become seriously ill, and some may even die, as a result of infection with influenza A/H1N1 2009. Reports indicated that this was particularly true of pregnancies in the third trimester. This indicates that pregnancy itself is indeed a risk factor for complications associated with influenza A/H1N1 2009. However, the limited amount of data that was available at that time precluded a clear appraisal. For this reason, the experts made no explicit recommendation for the vaccination of healthy pregnant women at that time. However, they did order that the vaccination should be made available to any pregnant women in the second and third trimesters who wanted it, in consultation with their doctor or midwife.

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

Recently published data from the United States, Canada, Australia and New Zealand confirm that pregnancy as such is a risk factor for complications associated with influenza A/H1N1 2009.[3,9,13,14] The problems are mainly associated with the third trimester of pregnancy, and are probably due – to some extent – to the elevated position of the diaphragm, which acts as an impediment to respiration. If, as a result of a complicated course of influenza A/H1N1 2009, it becomes necessary to ventilate a pregnant woman in her third trimester, then it will usually also be necessary to terminate the pregnancy by carrying out a caesarean section. This can be a cause of premature birth.

Recent publications have confirmed the risk of complications associated with influenza A/H1N1 2009 infections during pregnancy, even for pregnant women without any underlying disease. Accordingly, the experts now recommend that all pregnant women be vaccinated, from the fourth month of pregnancy.

The advisory report of 17 September 2009 stated that there is a lack of scientific data on the safety issues associated with the use, during pregnancy, of influenza vaccines and adjuvants (agents used to boost the immune response).[2] This involves what the experts consider to be a slight, theoretical risk, mainly during the first three months of pregnancy. It is during this phase that the organs develop and the foetus is most vulnerable. For this reason, the advice is still that vaccination should be used from the fourth month of pregnancy.

The experts also recommend that vaccination be carried out during the final weeks of pregnancy. There is evidence that vaccinating the expectant mother reduces the risk that her newborn baby will catch influenza.[15] Moreover, the second dose can be administered to the mother after the birth, with the previously stated purpose of reducing the newborn's exposure to influenza A/H1N1 2009.

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

Gezondheidsraad **President**
Health Council of the Netherlands

At your request, the panel of experts also addressed the question of whether there is any reason to attempt to procure a non-adjuvanted vaccine for pregnant women. Two vaccines are concerned. One vaccine is registered, but not available in the Netherlands timely and in sufficient quantity. It is uncertain whether the other vaccine will be registered in the Netherlands and, if so, when. In view of the above, the panel considers it neither necessary nor desirable that the option of vaccinating pregnant women in the second and third trimesters be deferred until further notice. This is further reinforced by the importance of vaccination and the positive assessment concerning the safety of the vaccine itself.

Yours sincerely,

(signed)

Professor J.A. Knottnerus
President, Health Council of the Netherlands

(signed)

Professor R.A. Coutinho
Director, RIVM Centre for Infectious Disease Control

P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

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P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

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P.O Box 16052
NL-2500 BB The Hague
Telephone +31 (70)340 66 25
Telefax +31 (070)340 75 23
E-mail: hans.houweling@gr.nl

Visiting Address
Parnassusplein 5
NL-2511 BX The Hague
The Netherlands
www.gr.nl

Annex **A**

The request for advice

Date of request: 29 oktober 2009; reference: PG/CI-2.966.756

On 8 May, 17 August and 17 September, you presented me with advisory reports concerning vaccination against New Influenza A (H1N1).

In the light of recent developments, and in line with my e-mail request of 15 October concerning this matter, I would like to request your advice on the following issues:

General
Since your advisory report of 17 September, has any new information become available in the following areas:

- your assessment of the current epidemiological situation; and your expectations concerning the possibility of adverse changes in the virus;
- your assessment of the chances that the virus will develop resistance to antiviral drugs.

Specific
Since your advisory report of 17 September, has any new information become available with regard to:

- the possible expansion of the current medical high-risk groups to include certain age-groups such as young people. An important point here is that any such expansion must be feasible, given the amount of vaccine available (see Annex 1) and the fact that we have passed the point of no return with regard to the initial vaccination for those in the current high-risk groups;

- the number of doses needed for full protection; reports have reached me that an application has been submitted for marketing authorisation for a single-dose vaccination;
- the risk to healthy pregnant women and the implications for vaccinating this group.

I look forward to receiving your written advice no later than Monday 9 November 2009.

The Minister of Health, Welfare and Sport,
(signed)

Annex 1 Delivery schedule pandemic vaccines

Our reference
PG/CI-2.966.756

	GSK			Novartis		
Date	number of doses	cumulative		number of doses	cumulative	
Monday19-10-2009				4.141.420	4.141.420	
Friday23-10-2009	757.000					
Monday 26-10-2009				2.791.000	6.932.420	
Friday 30-10-2009	360.000	1.117.000				
Friday 6-11-2009	234.000	1.351.000				
Thursday 12-11-2009						
Friday13-11-2009	332.000	1.683.000				
Friday 20-11-2009	541.000	2.224.000				
Thursday 26-11-2009				3.000.000	9.932.420	
Friday 27-11-2009	541.000	2.765.000				
Thursday 31-12-2009				2.900.000	12.832.420	
Friday 1-01-2010	3.244.000	6.009.000				
Sunday 31-01-2010				8.400.000	21.232.420	
Friday 5-02-2010	3.017.000	9.026.000				
Sunday 28-02-2010				1.800.000	23.032.420	
Wednesday 31-03-2010				900.000	23.932.420	
Total supplied	**9.026.000**			**23.932.420**		

Annex **B**

The experts

This advisory report has been produced jointly by the Health Council of the Netherlands and the Centre for Infectious Disease Control (part of the National Institute for Public Health and the Environment; RIVM), based on a document produced by the secretaries of these organisations and discussed at an expert meeting held on 4 November 2009. The meeting was attended by:

- Professor J.A. Knottnerus, *chairman*
  President, Health Council of the Netherlands, The Hague
- Professor J.G. Aarnoudse
  Gynaecologist, University Medical Center, Groningen
- Professor dr. S. Buitendijk
- Professor of integral preventive health care for children, Leyden University Medical Centre, Leyden
- Dr. M.A.E. Conyn-van Spaendonck
  Epidemiologist, RIVM-CIb, Bilthoven
- Professor R.A. Coutinho
  Epidemiologist/ virologist, Director of the RIVM Centre for Infectious Disease Control, Bilthoven
- Dr. P.J. van Dalen, observer
  Ministry of Health, The Hague
- Professor J.T. van Dissel
  Internist-infectiologist, University Medical Center, Leiden

- Professor W. van Eden
  Immunologist, Utrecht University
- G.A. van Essen PhD
  Research Fellow in General Practice, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht
- Dr. E. Hak
  Clinical epidemiologist, University Medical Center, Groningen
- Dr. W. van der Hoek
  Medical epidemiologist, RIVM-CIb, Bilthoven
- Professor R. de Groot
  Paediatrician, University Medical Centre St. Radboud, Nijmegen
- Professor M.D. de Jong
  Virologist, Academic Medical Centre, Amsterdam
- Dr. C. Herberts
  Medical Devices and Technology division (RIVM), Bilthoven
- Professor M. Koopmans PhD
  Professor of Virological Research for Public Health, Erasmus Medical Centre, Rotterdam, National Institute of Public Health,Bilthoven
- Professor T.W. Kuijpers PhD
  Child Immunologist, Academic Medical Centre, Amsterdam
- W. Luytjes PhD
  Netherlands Vaccine Institute, Bilthoven
- Professor J.W.M. van der Meer
  Internist-infectiologist, University Medical Center St Radboud, Nijmegen
- Professor J. van der Noordaa
  Virologist
- Professor M. Offringa
  Professor of clinical epidemiology in paediatrics, Academic Medical Centre, Amsterdam
- Dr. W. Opstelten
  General practitioner and staff member of the Netherlands Society of General Medical Practitioners, Utrecht (consulted in writing)
- Professor A.D.M.E. Osterhaus
  Virologist, National Influenza Center, Erasmus Medical Center, Rotterdam
- Professor J. Roord
  Paediatrician, Free University Medical Centre, Amsterdam
- Prof. dr. E.J. Ruitenberg
  Professor of international public health, Free University, Amsterdam

- Dr. H.C. Rümke
- Medical epidemiologist, Vaxinostics BV, Rotterdam
- Professor L. Sanders
  Child immunologist, Wilhelmina Children Hospital/University Medical Centre Utrecht
- Professor J. van de Velden
  University Medical Center St Radboud, Nijmegen
- Dr. M. Verweij
  Ethicist, Institute of Ethics, University of Utrecht
- E.G. Wijnans
  Clinical assessor, Medicines Evaluation Board, The Hague
- Professor M. de Visser
  Neurologist, Vice President of the Health Council of the Netherlands, The Hague
- Professor J. Wilschut
  Virologist, University Medical Centre Groningen
- Dr. Th.F.W. Wolfs
  Paediatric infectious disease specialist, Wilhelmina Children Hospital/University Medical Centre Utrecht
- Dr. K. Groeneveld, *scientific secretary*
  Medical immunologist, Health Council of the Netherlands, The Hague
- Dr. H. Houweling, *scientific secretary*
  Epidemiologist, Health Council of the Netherlands, The Hague

This report has been reviewed by the Standing Committee on Immunology and Infectious Diseases of the Health Council of the Netherlands.

The Health Council and interests

Members of Health Council Committees – which also include the members of the Advisory Council on Health Research (RGO) since 1 February 2008 – are appointed in a personal capacity because of their special expertise in the matters to be addressed. Nonetheless, it is precisely because of this expertise that they may also have interests. This in itself does not necessarily present an obstacle for membership of a Health Council Committee. Transparency regarding possible conflicts of interest is nonetheless important, both for the President and members of a Committee and for the President of the Health Council. On being invited to join a Committee, members are asked to submit a form detailing the functions they hold and any other material and immaterial interests which could be rele-

vant for the Committee's work. It is the responsibility of the President of the Health Council to assess whether the interests indicated constitute grounds for non-appointment. An advisorship will then sometimes make it possible to exploit the expertise of the specialist involved. During the establishment meeting the declarations issued are discussed, so that all members of the Committee are aware of each other's possible interests.