



To the Minister of Health, Welfare and Sport

Subject : Vaccination against pandemic influenza A/H1N1 2009: dosage
Your reference : -
Our reference : U 5630/HH/mj/824-Q Publication no. 2009/19E
Enclosure(s) : -
Date : November 25, 2009

Dear Minister,

The Health Council of the Netherlands and the National Institute of Public Health and Environmental Protection/Centre for Infectious Disease Control Netherlands are jointly monitoring developments relating to the pandemic of influenza A/H1N1 2009 at national and international level, offering advice where needed. In that context, the panel of experts held a telephone conference on 23 November. This was occasioned by press releases issued on 20 November by the European Medicines Agency (EMA) and the Dutch Medicines Evaluation Board. The press releases refer to a study into the effects of using one or two doses of Focetria and Pandemrix, the vaccines against influenza A/H1N1 2009. The amount of new information generated by this study is quite limited. Nevertheless, EMA sees it as evidence that a single dose of vaccine may be sufficient to generate an adequate immune response in healthy individuals from 9 to 60 years of age (in the case of Focetria) and in those aged 10 and above (for Pandemrix). On the basis of this data, EMA feels that certain age groups should also have the option of a single dose. EMA makes no comment concerning the number of vaccinations for individuals in the high-risk groups. For children below the age of 10 (for Pandemrix) or 9 (in the case of Focetria) and for adults above the age of 60 (for Focetria) it is recommended that two doses be given, regardless of the health status of the individuals in question. Responsibility for the dosage schedule selected for the various target groups for vaccination rests with national governments.

During the deliberations of 23 November, we discussed with the experts the issue of whether the above extension of the dosage instructions should have repercussions for public vaccination programmes in the Netherlands.

The experts noted that most of the data underpinning EMA's decision to extend the dosage schedule had been discussed by the panel of experts on previous occasions. In relation to the advisory report of 9 November, the experts are not aware of any new evidence that might cast a different light on the issue of the number of doses required for adequate protection. As yet, the



Subject : Vaccination against pandemic influenza A/H1N1 2009: dosage
Our reference : U 5630/KG/mj/824-Q Publication no. 2009/19E
Page : 2
Date : November 25, 2009

possibility cannot be excluded that the study results concerning the efficacy of a single dose 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. With regard to vaccination, the experts reiterated their conclusion that it should have the greatest and broadest possible efficacy (either for the protection of the vaccinated individuals themselves or that of vulnerable individuals entrusted to their care). They also take the view that current dosage recommendations (a vaccination schedule consisting of two doses) should be retained.

Based on the above considerations, the advice remains unchanged. All target groups for vaccination should receive two doses of vaccine. The target groups are: children from six months to four years of age; all those who are eligible for vaccination on the basis of a medical risk; healthy individuals aged 60 and above; pregnant women from the fourth month of pregnancy onwards; anyone sharing accommodation with infants below the age of six months; health professionals who may come into contact with patients in the medical risk groups; and the informal carers of individuals who are at very high risk of serious illness and mortality from influenza.

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



Subject : Vaccination against pandemic influenza A/H1N1 2009: dosage
Our reference : U 5630/KG/mj/824-Q Publication no. 2009/19E
Page : 3
Date : November 25, 2009

The experts

This advisory report has been produced jointly by the Health Council of the Netherlands and the Centre for Infectious Disease Control Netherlands (part of the National Institute for Public Health and the Environment; RIVM), based on telephone deliberation held on 23 November 2009.

The following experts participated in this deliberation or were consulted by letter subsequently:

- 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 Welfare and Sport, 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
- Professor M.D. de Jong
Virologist, Academic Medical Centre, Amsterdam
- Dr. G. Koch
Virologist, The Central Veterinary Institute of Wageningen University and Research Centre, Lelystad



Subject : Vaccination against pandemic influenza A/H1N1 2009: dosage
Our reference : U 5630/KG/mj/824-Q Publication no. 2009/19E
Page : 4
Date : November 25, 2009

- 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
- Dr. A.J. van Loon,
Gynaecologist, Martini Hospital Groningen
- W. Luytjes PhD
Netherlands Vaccine Institute, Bilthoven
- Professor F. Miedema
Immunologist, University Medical Center, Utrecht
- 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
- 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
- Professor M. de Visser
Neurologist, Vice President of the Health Council of the Netherlands, The Hague



Subject : Vaccination against pandemic influenza A/H1N1 2009: dosage
Our reference : U 5630/KG/mj/824-Q Publication no. 2009/19E
Page : 5
Date : November 25, 2009

- Dr. J. Wallinga
Population-biologist, RIVM Centre for Infectious Disease Control, Bilthoven
- J.M.L. Wentges-van Holthe, MD
Teratology Informatie Service, RIVM Centre for Infectious Disease Control, Bilthoven
- 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 relevant 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.