

Background

The Stichting Stralingsarm Nederland (SAN - Foundation for Minimal Radiation in Holland) and a number of other concerned groups against vaccination, have asked the Dutch government, in particular, the Ministry of Health (VWS) and the CBG (College Beoordeling Geneesmiddelen, the national responsible organ for controlling, evaluating and authorizing medical products in the Netherlands), for specific information concerning to the possible health risks of the planned vaccination against the Mexican flu, as well as the responsibilities, liability and claims settlements if health damage due to vaccination would indeed occur in the future.

One of the reasons for taking this action was the advice of the National Health Council (Gezondheidsraad) to the Minister of Health, to start vaccinating pregnant women with priority, whereas in this advice the Council emphasized that: *“there are virtually no scientific data available about the usage of the in the vaccine used adjuvants (immune-stimulating ingredients) during pregnancy”*. It seems against all logic and common sense, to recommend injecting pregnant women and young children/foetus, whose immune systems are still under development, with the untested influenza H1N1 vaccine, containing the adjuvant squalene, known to cause auto-immune diseases, based on the information currently provided to the public by the government.

The Ministry of Health (VWS) and CBG have refused to give this information, both on questionable grounds based on the Dutch Freedom of Information Act (Wet Openbaarheid Bestuur-WOB). VWS does not deny having this information in its possession, but refuses making this information public based on the exception grounds in the Freedom of Information Act.

For that reason, the Foundation SAN had to take further measures and has asked the Court in Zwolle to request the information previously asked from VWS and CBG, and to take a preliminary provision to not allow to vaccinations before the requested information concerning the health risks and resulting liability have been provided to the public at large and by specific means. The Court in Zwolle has declared itself competent to hear the case, and set the following date:
22 October 2009, at 14.00.

Right to information

Based on international law, the government has an obligation to guarantee the health of its population. According to governing case law of the European Court of Human Rights citizens have, based on this general international obligation, a right to be actively informed by their government about the dangers that jeopardize their right to a healthy environment. The Freedom of Information Act also underlines the obligation of the government to actively provide information (art. 8).

Obligation of the government

The obligation of the government to actively provide information applies also in respect of the possible negative effects cq. health risks of vaccination. The focus of the governmental policy regarding the vaccination-campaign has been, and still is, very one-sided and exclusively directed at the Mexican flu and the importance of inoculation. Without reservation, vaccination is pushed and pressure is put on the public by way of individual summons, inciting the public to let themselves be vaccinated as soon as possible. The government thereby embarks upon a “steering” policy and aims to influence the behaviour of

the public, by which its due care obligation, especially in respect of timely, adequate, transparent and trustworthy information, only (further) increases.

This active behaviour and policy of the government in support of the vaccination seriously contrasts its complete lack of action and policy in respect of providing information about the possible health risks and effectiveness of the vaccination in the short and long term.

Informed consent

Vaccination is, as yet, still provided on the basis of free choice. Before deciding whether or not to follow the government's advice to get vaccinated against the, still very mild, influenza H1N1 2009, citizens have a right to obtain complete and adequate information from the government about the possible health risks, on which basis only they are able to take a well-informed decision on what they allow to be injected into their body. Vaccination has to be based on free, prior and informed consent. It is therefore of the utmost importance that the government provides specific information about the ingredients of the vaccine that it is offering to the public (including vaccine-related ingredients, non-viral components, as well as the composition thereof), and information about the possible damaging health effects of the vaccines and its ingredients, as well as the safety and effectiveness thereof. Moreover, prior clarity and transparency is needed in respect of who, to what extent and on which basis, may be held liable should health damage (nonetheless) occur; e.g., did the government provide contractual liability waivers in respect to the vaccine-producers just like in the United States, and does liability therefore lie with the State or with each inoculated citizen on the basis of 'free choice'?

Safety of the vaccine

In the advice of the Health Council to the Minister of Health it also confirmed that the vaccine against the Mexican flu cannot be compared with a vaccine against a normal seasonal flu, as has often been suggested. But that to the influenza H1N1 vaccine certain "adjuvants (immune-stimulating products) are added, with which there has been only limited experience". It thus involves an entirely new systemic medicine which contains added, potential dangerous and insufficiently tested ingredients.

Special concern and ambiguity exist in respect of the adjuvant 'squalene' which is added to the vaccines purchased by the government (GSK-pandemrix and Novartis-Focetria), and which seems necessary to realize a large (worldwide) production of vaccines. Within the scientific community as well as in practice, there exist a founded indication that the manufacture of this vaccine with the adjuvant squalene can cause auto-immune diseases. Various independent scientific research has concluded that squalene can result in health damage, especially in the long term. It has also been related to the Anthrax vaccine which caused the so-called Golfwarsyndrom.

The United States' FDA (still) prohibits the use of squalene, whereas the comparable European authority, EMEA allows its usage based on its experience for over 10 years with the Chiron-Fluad seasonal flu-vaccine for Seniors, to which squalene was also added. Unclear is to what extent especially long term effects, can in practice be tested or researched with "seniors".

Squalene is a substance existing naturally in the body, a precursor of cholesterol. There is an essential difference in taking squalene in through food and injecting it directly into the body. In essence the adjuvant squalene is not necessary for making the vaccine work. However, without squalene more antigenes would be needed, and those are only available in limited amounts due to current production-limitations. Squalene puts your immune-system on a higher alert, so that less antigenes are required in the vaccine to have the same effect. But the problem is that by doing such, the body can produce anti-bodies against squalene itself, and so attack the squalene of its own body, and thus leading to auto-immune diseases, as confirmed and researched by independent scientists.

Liability for possible health damage in the short and long term

There is no clarity about the liability for vaccination related health damage on short or long term. On this topic no information is provided by the government. In case health damage does occur as a result of vaccination, it is important for each citizen to have certainty and knowledge about who and when he can claim compensation from, e.g. his physician that injected him with the vaccine, the vaccine-suppliers or producers, or the government. At the government created information-line about the 'flu-pandemic' (0800-1100) it is explained that since vaccination is based on free choice, those who take it will therefore carry full responsibility and liability for possible adverse health effects of vaccination.

The past has taught us that to blindly trust the information and authorization of a certain medical product in some cases still could lead to dramatic health damage, on the short as well as the long term (DES, Softenon, Vioxx, Anthrax-vaccine etc.). This concerns medical products that *did* undergo adequate and the customary required long-term clinical trials.

The same confusing and contradictory information available has also created doubts and uncertainty in respect of the recent campaign (executed even on the level of schools) to inject young girls with a vaccine to prevent a HPV-infection, that could *possibly* lead cervical cancer. Also then the government refrained from giving the public information about possible adverse health effects (on short and long term). A significant part of the target group thus decided not to get inoculated, based on the gut feeling that government information on this subject was not complete and not trustworthy.

Required/forced vaccination and other means of coercion

Vaccination is not (yet) obliged. However, in theory, this could (quickly) change; even beyond an active decision or will power of the Dutch government.

On 15 June 2007, the International Health Regulations (IHR), established under the auspices of the WHO, entered into force. It is binding on all 194 Contracting States including The Netherlands. Each Contracting State is obliged to implement this Regulation into national law and policy, which in The Netherlands was done by Wet Publieke Gezondheid (WPG, Law on Public Health) and the regulations and guidelines based thereon.

The IHR provides measures that will have to be followed worldwide in order to protect public health, among others, in respect of international travel. Such measures also provide for, *inter alia*, required or forced vaccination, quarantine, isolation and medical examination for travellers that are regarded as 'suspects' upon their arrival of the 'point of entry' in each Contracting State. A traveller needs to be in possession of an international recognized and adopted WHO certificate, which states that he has been vaccinated with a vaccine approved by the WHO. Alternative flu protection measures, including vaccines not approved by the WHO, are thus not valid.

The IHR 'regime' and its measures can only be enforced in case of "a public health emergency of international concern", of which the decision authority lies only with the WHO Director General. Also the decision to take certain measures, including which kind of measures, fall ultimately only within the authority of the WHO Director General.

In June 2009 the WHO declared the spread of the "H1N1 influenza" to a pandemic (Phase 6); on the basis of preliminary information. Despite the fact that it is now evident that the Mexican flu appears to be rather mild in respect of its extent and seriousness even in relation to a normal seasonal flu, the pandemic-status is currently still in force. It would have been reasonable and correct if the WHO would have adjusted the pandemic Phase 6 to Phase 3 or 4. A Contracting State is obliged, even if it has other views, to follow the WHO in this and act in conformity with the measures implemented in respect of the "pandemic" scenario.

The Dutch government states that these IHR measures concern only non-binding recommendations that a State will not necessarily have to implement. It is however unclear to what extent this non-binding status relates to all measures, (some IHR special health measures

seem not to fall within this category). In addition, the government explicitly states that in case of WHO recommendations, there will be “serious international pressure” to implement those recommendations (even against logic). Moreover it seems that some measures, for instance those involving border regulations in respect of travellers (including possible forced or required vaccination), fall within the exclusive competence of the European Union. The Netherlands could therefore be required to follow the IHR recommendations in case the European Commission so decides, without approval of its Member States. Finally, the Dutch government has no influence over the extent to which other IHR Contracting States do implement these measures, and also, the extent to which an interference with or violation of our basic human rights may occur in those States

The fact that the IHR is applicable to travellers, raises the question to what extent Dutch travellers can be protected in foreign countries against forced or required (non-tested and potentially dangerous) vaccination, isolation and medical examination. This phenomenon would then indirectly still result in ‘coercion’ for the Dutch citizen, i.e. to rather take the vaccination ‘freely’ in The Netherlands.

In conclusion: As long as there is “pandemic-status” active, the WHO may at any given moment declare that it is necessary to take certain health measures that Contracting States will implement. This means that the possible transboundary IHR measures of coercion (including forced/required vaccination) can be declared applicable, whereas, especially in the absence of a factual emergency, they constitute a violation of the constitutional rights, various treaties on human rights and rights laid down in other international legal instruments.

EMEA/FDA: A ‘pandemic’ to justify fast-track authorization and post-clinical trials

The current pandemic-status does not only seem to be crucial for authorization to take measures of mass vaccination of the world population, but also provides the justification to allow accelerated authorization and testing procedures. According to the European Commission, Europe is “well prepared” for a pandemic since there are measures in place to allow “*fast-track scientific assessment and subsequent authorisation for marketing of human influenza vaccine* and “*to authorise the distribution of unauthorised vaccines in an Influenza pandemic*”.

Moreover, it is not known whether adequate and comprehensive scientific research, normally required by the EMEA/FDA, can or will take place soon, and whether the vaccines will be tested “*in vivo*”, and if so, whether this will be done with or without the potential dangerous adjuvants. Since if prior tests are done without the adjuvants, the results would not provide useful information as to the potential adverse health effects involved, which are mostly caused by those adjuvants.

EMEA states in this respect:

“As with all medicines, rare adverse reactions may only be detected once the vaccines are used in large numbers of people. The Agency has requested that vaccine manufacturers implement plans to actively investigate and monitor the safety of vaccines as soon as they are used across the EU, so that action can be taken as early as possible if a safety issue emerges. As part of this, the manufacturers have committed to carry out post-authorisation safety studies in about 9,000 subjects for each vaccine.”

From this statement can be concluded that the required clinical trials for the recent mock-up vaccine, loaded with the current H1N1 virus (currently still under development), will take place *afterwards* (“*post-authorisation*”), and not by an independent official institution but by the “*manufacturers*” themselves (!), and with those target groups that have been vaccinated by ‘free choice’, such as pregnant women and children. Furthermore, it is unclear under which conditions and guidelines such ‘post-authorization’ and risk-analysis will take place.

Derogation of fundamental human rights in case of a WHO "pandemic"-status

Since the government ("www.grieppandemie.nl") and the WHO, whether justified or not, speak of a pandemic, ("a public health emergency of international concern"), the special IHR regulations can enter into force on very short notice, such as required e.g. forced vaccination, quarantine, isolation, medical examination, and WHO vaccination certification.

In such a case, the constitutional guarantees for basic human rights can therefore automatically be set aside in the Contracting Parties, which leaves the door open for extensive interferences with the fundamental human rights, leaving victims thereof with no available and adequate legal procedural means or remedies. In respect of such a WHO 'pandemic' declaration and measures based thereupon, potentially involving far-reaching limitations of fundamental human rights, a citizen has no means available for legal examination. Moreover, based on Dutch law (WPG – Law on Public Health) there are legal consequences related to the non-fulfillment of such measures (e.g., a refusal of quarantine and isolation qualifies as a crime punishable with a jail sentence of a maximum of 4 years!).

In case there would be a deadly virus that seriously threatens the world population, quickly spreads internationally and which already in practice killed thousands, if not more, of people, then one can indeed speak about an "international health emergency", the seriousness of which would justify a certain derogation or limitation of specific fundamental human rights. However, the question is, whether in such situation, this rigid regime of available measures of coercion, like forced vaccination, would be functional. In such a scenario it is far more probable to focus on measure of '*ordre publique*', since the widespread fear and panic, even a large scale 'run' on the available vaccines, would easily lead to disorder, especially if, like in most cases, there is a vaccine-shortage. The logic and factual necessity to concentrate on forced vaccination, coercion- and penalty measures seems completely absent in such reality. Therefore, the government is well-advised to reconsider the necessity of measures of coercion should the WHO and the pharmaceutical companies be indeed capable of producing a well-tested and completely safe vaccine-product. It is evident that on the basis of common sense, any citizen would not only take such vaccination based on its free will, but would even demand such vaccination from their government. The measures of coercion are apparently considered to be necessary in view of the knowledge and anticipation of a growing distrust in the public at large about the safety of vaccines in general, and untested vaccines in particular.

In fact, the entire WHO/IHR legal framework, as established probably with good intentions, provides a serious gap and possibility for a complete and worldwide 'hijack' to the benefit of politico-economic powers and/or industrial consortia, for economic gain or with an entirely alternative agenda, which has nothing to do with ensuring public health, and far beyond that what the Contracting States are presented or told to believe. Through this international IHR based regulatory framework our entire well-established regime of fundamental human rights and guarantees can be put at risk at will, *i.e.* by mere declaration of the WHO Director-General. It is clear, that "by activation" of such totalitarian legal mechanism, it would invite *détournement de pouvoir* at all governmental levels.

Combined with this, it is of great concern that there is hardly or at least no transparent control over the factual content of the vaccines, which, if an agenda would not be focused on health improvement but economic gain or otherwise, this would lead to serious consequences. The IHR regime as currently implemented worldwide, provides no protection against large-scale misuse or hijack. It is up to the individual governments of the Contracting States and the judicial authorities to seriously and urgently (re-)evaluate the validity of the IHR, and related implemented legislation, in its current form. Finally, since the IHR contains no rules on termination or withdrawal, it is necessary to find other possibilities should Contracting States wish to withdraw from the application of the IHR.

Request to the Court

Based on the above, the Foundation SAN and interested parties, have asked the Court to request from the Ministry of Health and CBG with urgency, the following information that is of the utmost importance for the health of each Dutch citizen:

In respect of the potential measures that invade or limit the right of freedom:

- adequate and independent evidence of the factual existence of an ‘international emergency’ or ‘pandemic’ with serious health risks for the world population, justifying the specific measures that jeopardize human rights taken or to be taken in the future;
- when, and under which specific situations and conditions, measures based on the WHO IHR and implementing national legislation will be taken which imply a derogation from rights of freedom or other measures implying force (i.e. forced vaccination, quarantine, isolation, violation of privacy etc.)
- the legal means available for citizens to defend themselves in case the WHO recommends such ‘force’ measures and the government is considering to follow-up and implement those measures;
- information and clarity about potential forced or required vaccination for travelers, the time-frame within which such measures can be taken, which authorities/persons can make such a decision, and the extent, form and possibility of legal protection in a foreign country against such measures of forced vaccination, medical examination, isolation, quarantine, etc.
- under which circumstances the government will decide to follow and implement WHO special recommendations and/or special health measures, as indicated in the IHR (especially art. 18 and 31)

In respect of the vaccination program/campaign:

- information as to the exact ingredients of the vaccine chosen and bought by the government, including the composition and proportions thereof, as well as the virus-variations used;
- the manner in which the vaccine is produced/bred (on eggs or otherwise), where it has been tested in a clinical trial or study, by whom and when, and whether these tests were done with or without the adjuvants, and the results thereof;
- complete and comprehensive information regarding the (health) risks of the vaccine, the non-viral components thereof, the adjuvants and other non-vaccine related ingredients;
- a complete overview of the documents relating to the regulation and contractual agreements as to the determination of liability of the government, vaccine producers, doctors, and the persons being vaccinated; in addition clear and precise information about who will be liable under which circumstances, as well as the extent to which the vaccinated person will be responsible for potential health damage as a consequence of the vaccination;
- clear and precise evidence of the proportionality of the measures taken, which should take into account:
 - the expected factual health risks for the population of the current influenza H1N1, as yet not mutated into a deadly variation, in case a person decides not to take the vaccination (including all other possible consequences of such decision, such as moral pressure, stigmatization, criminal offence, etc.)
 - the health risks versus the effectiveness and safety of the vaccine, including all added adjuvants and non-viral related components;
 - the specific risks for especially pregnant women and their unborn and young children, taking into account the short and long term risks imposed on their still sensitive immune system which is still under development;

- scientific based and researched advice which provides clarity and certainty as to what the safest moment is and the safest dosage, if this would exist at all, within the period of pregnancy in which a vaccination can be applied without (immune-related) damage to the foetus;
 - the health risks that can be emerge as a consequence of double vaccination with a intermediate time period of 3 weeks considering that the first vaccination will provide a protection level of merely 40%;
 - the fact that there currently is no longer a duty for physicians and doctors to communicate and record a Mexican flu cases, and the possible consequences for a person that receives the vaccine when he already had the Swine flu, as well as the potential health consequences of a combined vaccination of a (previous) seasonal flu vaccination or other previous vaccinations, together with the influenza H1N1 vaccination;
 - complete and independent safety analysis and overview of the various but limited vaccine producers, their studies tests and results of trails with that vaccine and the contracts and licenses related to that producer, also the conditions under which the government has contracted those producers, including any waivers and conditions as to potential damage claims and the procedures thereof (claims compensation mechanisms).
 - (anonimised/objectivised) notes and documents in respect of the EMEA/FDA (etc) decisions and meetings, in which and based on what grounds, a decision was made for fast track authorization of the tests for the H1N1 2009 vaccines;
- finally, also on the basis of the above, evidence of proportionality of any planned and possible measure in relation to the pandemic influenza H1N1 in relation to the fundamental human rights applicable under international treaty and customary law, regional law, as well as the Constitution.

Secondly, in view of the potential health risks of the population by vaccination, and the matter of urgency, since vaccination is planned for October/November, the Foundation asked the Court to declare that the government, on the basis of the above, will provide this information and adequately inform the public of the possible health risks, *before* starting with the (first) vaccinations.