

The Committee on the Constitution (Parliament of Sweden)

The Riksdag

Attn: Head of Secretariat Bertil Wennberg

100 12 Stockholm

23 November 2009

Request to propose that a scrutiny be made of the Government's handling of swine flu and of the vaccine against the swine flu pandemic.

In accordance with Chapter 3 §7 of the Riksdag Act, Leif Arnold herewith requests that the Committee on the Constitution proposes to the Riksdag that a scrutiny be made of the Government's handling of the swine flu epidemic and also of the swine flu vaccine against the pandemic (Committee initiative) on the following grounds.

A request has also been submitted to the Parliamentary Ombudsman (JO) to scrutinise the handling of this case by the National Board of Health and Welfare, the Swedish Institute for Infectious Disease Control, the Swedish Civil Contingencies Agency and the Medical Products Agency. Pursuant to the special provisions thereon JO and KU should co-ordinate their investigations.

1. Helsinki Declaration

The Helsinki Declaration was drawn up and adopted as long ago as 1964 by the World Medical Association (WMA). The Declaration is not a legally binding document under international law, but merits full authority by virtue of its codification in or influence on Swedish laws and regulations in Sweden.

The current Swedish vaccination campaign does not comply with the Helsinki Declaration and the rules regulating ethical principles that apply to medical research involving human beings. The Government and governmental authorities have stated in several appearances on TV that, for example: "The vaccine that is being developed is after all an entirely new vaccine so of course it has never been tested in the field ..."; "this is the first time in world history that

we have the possibility to ...”, and “the protective effect of the vaccine is unknown, but we believe ...”. Such guesses and assumptions, which, as can be seen, are not based on scientifically proven facts, shall not be tolerated by the Riksdag.

Charlotte Bergqvist at the Medical Products Agency refers to studies and the results of such studies and the fact that these are now in progress. Charlotte Bergqvist also comments: “After all, we don’t have the data yet...”, “we are expecting the results of further studies within the coming months”. Moreover, the Pandemrix product resumé refers to studies and points out that there is a particular interest in side effects that are fatal, life-threatening, unforeseen or otherwise of particular interest. Furthermore, the County Council has released information to the effect that only serious and unusual suspect side effects are to be reported. The County Council also states that reports relating to children and pregnant women are of particular interest. The Government has thus permitted the manufacturer, GlaxoSmithKline (GSK), to carry out large scale, controlled studies of pharmaceuticals on unwitting individuals in Sweden.

## 2. Supply agreement in breach of policy

The Administrative Court of Appeal has recently handed down a decision refusing disclosure of the Glaxo agreement on the grounds of alleged business secrets and the national interest. An appeal against this decision has been submitted to the Supreme Administrative Court.

## 3. Rights of the individual

Moreover, pursuant to policy for research ethics, the individual shall in principle also be informed if he or she is participating in a research project, even if the study is entirely free of risk to the individual. The reason is respect for personal rights and privacy and the underlying demand for respect for the individual. Such a requirement to respect the rights of the individual is also based on the Swedish constitution.

Alleged and as yet poorly substantiated evidence for a pandemic, using abysmal logic and an artificially created queue panic, can under no circumstances mean that the Government is free to breach official policy for research ethics, the Helsinki Declaration or the Swedish constitution.

#### 4. Other offences by the Government

The research study has been preceded by intensive and false propaganda. Consequently, participation in the vaccination campaign is not based on an informed and voluntary decision, which conflicts with the WMA guidelines.

Moreover, given the throughput rates for vaccinations that have been referred to there is no reasonable possibility of the personnel assuring themselves that patients have been given the all-round information required by the rules to enable their decision to be deemed to be well informed, which the Standing Committee should investigate as a breach of the requirements of the Nuremberg Code, i.e. voluntary, well informed consent.

The WMA also stipulates the need for informed consent. By informed consent is meant that the patient is aware of the risks, if any, to which he or she may be exposed and that he or she may be given a placebo or a drug. Children are also entitled to informed consent. However, the Government has not bothered to give children information suitable for their age.

The Government must be considered to have breached the policy on research ethics when it used words like “invited”. According to established ethical practice the word “requested” should be used rather than “invited”. The latter verb implies that it is some form of privilege to be allowed to participate, and it can thereby conceal that fact that participating can also involve risks and discomfort.

#### 5. Lack of patient safety standards

All pharmaceuticals, including vaccines, shall be tested for safety and efficacy in accordance with applicable established safety and efficacy standards. Without testing for safety it is not possible to conclude that the benefits outweigh the risks or that the vaccine is either safe or effective. The underlying safety of this vaccine, Pandemrix, rests on insufficient studies and inadequate scientific facts that verify that the vaccine was/is safe to give to human beings. It has been claimed that Pandemrix is safe to give to children, pregnant women and the rest of the Swedish population. Pregnant women have also been told that the vaccine provides indirect protection for the child when it is new-born. It is claimed in the product resumé:

“There is very limited experience with children between 3 and 9 years of age, and there is no experience at all regarding children under 3 years of age or regarding children aged between 10 and 17.” ... and “at present there are no data pertaining to the use of Pandemrix during pregnancy.” In other words, there was no experience whatsoever, or it was very limited at the time when mass vaccination against swine flu started.

#### 6. Absence of tests on pregnant women

Formerly, it was a principle not to give medication to women during their pregnancy, simply because the risks to the child are too high. In this case, the Government has departed from these principles. Moreover, the vaccine has never been tested on pregnant women. The Government claims that it has carried out a risk/benefit assessment, and that this shows that “the benefits outweigh the risks”. Such published scientific literature as is available describes an entirely different situation. Abbreviated presentation: by activating a pregnant woman’s immune defence system during the middle or later period of her pregnancy there is a significant rise in the risk that the child will develop autism during its childhood or schizophrenia during its teens or later.

*Source: Smith SEP et al. Maternal immune activation alters fetal brain development through interleukin-6. Journal of Neuroscience 2007;27: 10695-10702.*

The risks to which this vaccine exposes the foetus are huge. Strictly statistically the risk that a pregnant woman will end up in hospital as the result of a swine flu infection is 1 in 300,000 pregnant women. Is the government using common sense in its reasoning? Statistically, the risks to which the vaccine exposes a pregnant woman is 100% per one pregnant woman, and swine flu as such represents a risk of ending up in hospital of less than 0.32% per 100,000 pregnant women.

#### 7. Risk exposure of young children

The Medical Products Agency announced on 12 November 2009 that all children under the age of three should be vaccinated against swine flu. The decision was based on a new study that covered 51 children aged under three, as well as the experience up until now of giving the vaccine to children aged between three and six, and to infants under the age of three who

belong to some form of risk group and who had been vaccinated against swine flu.

Furthermore the Medical Products Agency announced: “the study shows that young children also receive good protection with this vaccine and that there are no other side effects other than those seen amongst older children.”

The studies referred to are insufficient, as reference can only be made to side effects that have been verified during the last few months. We therefore have no idea about the side effects or their scope. Moreover the long term harm caused by the vaccine is also unknown. One of several substances that are clearly unsuitable as components of this vaccine is ethyl mercury, as it is transformed into inorganic mercury in the body and can thus cause damage to brain cells, for instance, particularly during the development stage of the foetus and in infants. Ethyl mercury can readily pass through the blood/brain barrier and can therefore easily end up in the brain.

In July 2009 a research report was published which also revealed severe cell injuries caused by thiomersal. The report, which is unobjectionable, revealed the following: the mitochondria are so severely damaged that they no longer function normally, reduction in the body's protection against free radicals, cell degeneration and cell death. The government has evidently also ignored this report. Thiomersal could have been removed from the vaccine, but owing to the government's frugality a vaccine containing thiomersal was ordered nonetheless. I am astounded at the government's lack of knowledge, and even more at the government's lack of concern about the possible long-term harm caused by this vaccine.

Furthermore, on the very day the Medical Products Agency made its decision, a two year old died in Finland, even though it had been vaccinated against H1N1 swine flu. According to a press release from the HNS hospital district the child became ill at the beginning of the week. On Wednesday it was admitted to hospital. By then one week has passed since the child had been vaccinated against H1N1. It is my view that the aforementioned fatality proves that the vaccine does not provide effective protection for a child under the age of three, and that fatalities cannot be ruled out amongst children who have been vaccinated against swine flu. As usual the cause of the fatality is explained away with the words “the exact cause of death is not known.”

## 8. Consequences for healthy individuals

I would also like to take this opportunity to express my views about giving the flu vaccine to healthy individuals. Naturally acquired immunity after having had flu is the best form of protection in the long term. So why should we deprive the population of the best protection? The supposed savings it is now claimed we are making by vaccinating the Swedish population will only result in a deferral of the problem and the cost.

My argument was confirmed by state epidemiologist Annika Linde when she stated on the morning news: “Having had numerous flu infections during one’s life has helped to build up this immunity,”.... “As with all diseases it is better for one’s long-term immunity to have a natural infection rather than be vaccinated,” .... “We now have a far better vaccine than the usual flu vaccine, which should provide longer immunity and in the worst case scenario we will have to give a flu jab now and then, to retain the immunity.”

## 9. Other Government irregularities and shortcomings.

The Government has claimed that it is above all young healthy individuals who are affected by swine flu. This is not the case. An epidemiological study that was carried out by the French Institute for Public Health (*Institut de Veille Sanitaire InVS*), and published on 20 August 2009 demonstrated something quite different.

The number of cases of swine flu around the world has been hyper-inflated.

I would also like to draw the attention of the Committee on the Constitution to the fact that the WHO has, during the course of the process, altered the definition of pandemic. The phrase “with a large number of dead and sick” has been removed, and the new definition can also cover the average seasonal flu.

The Government has failed in its crisis planning, by not introducing travel restrictions, by not making quarantine arrangements at airports, no infrared cameras were installed etc. It was pure luck that swine flu (the pandemic) and its spread of disease and fatalities were not worse. Will we be so lucky next time?

## 10. Request

The Committee on the Constitution should therefore without delay and on its own initiative investigate whether the Government, through its responsible ministers, has acted in breach of these rules by virtue of its direct and explicit participation in the decision-making and planning of the vaccination campaign by the relevant authorities.

Given this background information I would therefore request that the Committee takes a committee initiative to scrutinise the Government and its handling of the swine flu and the pandemic vaccine for the same. This is a matter of urgency and significant public interest.

I request to be called as a witness by the Committee on the Constitution.

Stockholm, as above.

*Leif Arnold c/o Center för Miljö- och Energiforskning Sverige AB*

*Box 201 03*

*161 02 BROMMA*

*SWEDEN*

*e-mail: [arnold@cmef.eu](mailto:arnold@cmef.eu)*