EVM statement to the Council of Europe hearing

"The handling of pandemic preparedness: more transparency needed?"

On the motion 'Faked pandemics – a threat for health'

Strasburg, 26 January 2010

Mister Chairman, Committee Members,

Thank you for the opportunity to address this Health Committee hearing on the important topic of pandemic influenza. My name is Luc Hessel, and I am here on behalf of the European Vaccine Manufacturers group – EVM – which represents the main pharmaceutical companies involved in research, development and production of vaccines in Europe.

Let me first express our concern about the terms of this motion, which sound inappropriate to those who are familiar with the actual way pandemic preparedness has been conducted.

EVM rejects the accusations of inappropriate behaviour of vaccine manufacturers in their response to health authorities in their fight against the H1N1 2009 pandemic.

I would like now to offer the following comments on the three main allegations, 1) influencing policy makers, 2) making undue profits and 3) delivering dangerous vaccines.

To the first point, the vaccine industry did what it was asked to do: responding to those in charge of defining policies in full respect of international regulations and through transparent practices.

Those in charge of defining policies and critical decisions on how and when to react to a pandemic are scientists, international institutions and governments.

The industry's role is to develop, to produce and to deliver safe and effective vaccines in a timely manner in order to meet public health expectations and to respond to government's requests. Working together with all relevant stakeholders is necessary and normal practice. It is governed by stringent International Health Regulations and rigorous safeguards against conflicts of interest.

This is of course a critical contribution, because vaccines are complex biological products, requiring specific production processes and long manufacturing lead times. Therefore decisions regarding vaccine needs have to be made early enough. They can only be based on the best available data at that time. Manufacturers are thus asked to provide authorities with information related to production capabilities to assist their planning efforts.

While this contribution is important, its aim is to *inform* public health authorities on the relevant technical background to optimize a global pandemic response.

Needless to say that, in order to meet these challenges, manufacturers made huge investments. This includes pandemic vaccine research and development, clinical studies, adaptation of production facilities and the requested expansion of manufacturing capacity to meet a global demand. It has also to be understood that this investment was undertaken at industry's risk, despite uncertain financial returns. They illustrate our commitment to public health, as the central part of our corporate social responsibility.

In this context - and to the second point - industry responded quickly and effectively and was able to deliver vaccines ordered by governments.

Pandemic vaccines are, by nature, unique vaccines made on specific request by health authorities and delivered when governments decide to order them. In the perspective of a threatening avian flu pandemic, some governments decided to secure vaccine procurement through contractual agreements with manufacturers, according to their own requirements. By having agreements in place in advance, governments avoid the need for complex negotiations following the declaration of a pandemic, when time is tight and governments are likely to be competing for supply. These so-called "advanced purchase agreements" were designed to ensure that manufacturers are ready to implement a rapid and efficient pandemic response.

Some governments did it for the H5N1 threat and applied them to the H1N1 pandemic. But most of the H1N1 vaccine supply agreements were finalised during the third quarter of 2009.
It must be clearly stated that many of these supply agreements were in the form of public tenders. Vaccine producers were treated in the same way as other suppliers.

Regarding the allegation of making profit out of this situation and considering the investment made in vaccine development and production, I must remind that industry responded to requests from WHO and governments to have a fast access to large quantities of vaccines. In any way it is too early to speculate on the overall return on investment for the vaccine industry.

Let me add that manufacturers have also made significant efforts in improving global access to pandemic vaccines. Individual companies are donating 160 million doses of vaccines to WHO for use in developing countries (GAVI eligible). Individual producers are reserving production capacity for developing country supply. Differential pricing approaches have been implemented to make vaccines affordable to middle- and low-income countries.

These measures demonstrate that industry has been a reliable and responsible partner in the fight against pandemic influenza.

To the third point, I confirm that pandemic vaccines were properly developed and tested, and have been safely used in millions of European citizens

A number of misconceptions exist regarding H1N1 vaccines that I would like to dispel.

For the first time in history, vaccines were available shortly after the start of a pandemic. **But this does not mean they have been *"insufficiently tested"***. Such a rapid response was only made possible thanks to a decade of extensive efforts in research and development, industrial operations, and to a 60-year experience with seasonal flu vaccines.

In fact, H1N1 vaccines are essentially developed, manufactured, controlled and evaluated using the well-established procedures for seasonal influenza vaccines which have proven to

be efficacious and safe in billions of people during the past 60 years. They have also benefited of recent progress in formulations and technologies used in other vaccines.

H1N1 vaccines have demonstrated their efficacy and safety in specific clinical studies in thousands of subjects in a range of age groups, conducted in respect of strict regulations. The European regulator, the European Medicines Agency – EMA - and national regulatory agencies have established processes to fast-track the appraisal of pandemic vaccines in order to allow their rapid use without compromising safety.

Finally, a comprehensive range of measures is in place to review and monitor the safety of H1N1 vaccines. More than 38 million people in Europe have been vaccinated. The latest results from this surveillance have been issued by EMA on January 20. They estimate that 34 million people, including more than 258,000 pregnant women, have received at least one dose of the centrally-authorised vaccines that in the European Economic Area. The vast majority of reported suspected adverse reactions are non-serious and the agency concludes that *"the benefit-risk balance of the pandemic vaccines continues to be positive".*

To conclude, I hope this short presentation gave you an insight into the actual role of the European vaccine industry in pandemic preparedness as a responsible partner. I hope it helps address the concerns raised by this motion, and I hope it helps you understand why EVM strongly rejects the allegations made in this motion.

The EVM and its member companies are committed to their continuing contribution to pandemic preparedness and more globally to their long term contribution to the health of European citizens by developing and providing vaccines for public health needs.

Thank you again for this opportunity to contribute to this hearing.

I will gladly answer any questions you may have.