



PANDÉMIES, ÉTHIQUE, SOCIÉTÉ



The European Vaccine Manufacturers (EVM) viewpoint

Bernadette Hendrickx

Chairman of the Regulatory Working group, European Vaccine Manufacturers (EVM)

The group of European Vaccine Manufacturers¹ was founded in 1991. Among other features, we can mention it has the highest R&D intensity in Europe as well as a strong industrial infrastructure.

We have to develop vaccines both for the developed and the developing worlds. Our group bears a huge responsibility in pandemic preparedness. Roughly 50 % of the European vaccine production is distributed outside Europe. The manufacturing of vaccines for the world takes place in only a few countries. What would happen if they had to close their borders? Would a few states be tempted to prevent flu vaccines exports? We are not able to provide clear answers to these questions. A discussion aimed at setting a commitment is currently under progress with the WHO.

Capitalizing on the growing seasonal flu vaccine production facilities

The fact that manufacturers have to produce seasonal vaccines has to be emphasized. Every year, two different vaccines are put into market because agendas including strain differentiation for flu in the northern and the southern hemispheres are decoupled. Regarding seasonal vaccines (true for all vaccines), Europe and the US have different regulators. Furthermore, their markets are not ruled in the same manner. And both the US and Europe have regional manufacturers.

In the field of pandemic preparedness, our basic commitment is to provide as much pandemic vaccine as quickly as possible after the pandemic has been declared and/or in anticipation of the first wave. The clock will be ticking between the apparition of a new strain and the development of an

¹ It includes: Baxter, Berna (Crucell), GlaxoSmithkline, MedImmune, Novartis Vaccines, Sanofi Pasteur, Sanofi Pasteur MSD, Solvay and Wyeth.

effective vaccine. We should not forget that, in vaccine development, a lot of parameters are strain-dependent. Depending on the strain, the amount of vaccine antigens required for triggering an immune response can vary a lot. And we theoretically need two doses to mount an effective response. But industry has developed antigen dose-sparing strategies (by adjuvantation) that could potentially solve the pandemic supply issue and make pre-pandemic strategies a reality. Generating the expected immune response with only one vaccine would be a challenge. On the basis of a continued growth in seasonal vaccine usage, a monovalent pandemic dose production capacity could be sufficient to cover most of the global population by 2010 on a year basis.

Can the emergency of vaccination be detrimental to the safety of a new vaccine usage?

Not all vaccines have a 100% efficacy, we cannot expect to have a 100% efficacious pandemic vaccine, which will probably be. The efficacy of the pandemic vaccines can only be evaluated during the pandemic and results available at best during the pandemic. The pandemic vaccines as currently studied did not show any concern regarding safety. However, as already experienced several times, it is unavoidable to observe adverse events in temporal association to the vaccine during mass vaccinations.

The question that arises is the liability in case of harmful side-effects. Would it be the manufacturer or the authorities? The efficacy and safety of the vaccine in children needs also to be addressed as few studies have been carried in this specific population.

What kind of prevention can be reached with vaccines?

Stockpiling vaccines is based on the possible cross reactivity of the stockpiled vaccine and the pandemic vaccine. Though stockpiling of a given vaccine has its limits regarding stability. Indeed, once the shelf life is reached the vaccine cannot be used anymore which then requests a renewal of the stockpile

We are certain that we have the duty to make an effective vaccine available with the needed quantities .

But everything remains open and uncertain when we raise the questions “by which ways?”, “to who?” and “when?”.