A "Public Private Partnership" on European Pandemic influenza vaccines

The EVM members are committed to contributing to global public health and to addressing the challenges posed by the threat of an influenza pandemic. In this respect, EVM supports the principle of a "public private partnership" on European pandemic influenza vaccines. However, EVM considers that the draft proposed has to be reviewed taking in account a slightly different approach. EVM believes that the contribution of each partner needs to be clarified to avoid overlapping work, responsibilities and maximise each other's competencies and know-how. Furthermore, the role of the MSs and the Commission should be enhanced in the PPP model together with the creation of a formal platform to coordinate and manage the different actions to be undertaken under the "PPP".

General comments

Industry's contribution to the "PPP", as set out below, is the development of the influenza vaccine. This includes:

- Vaccine formulations
- Clinical lot production
- Pre clinical testing
- Clinical testing
- Mock-up registration file
- Production scale-up
- Shipment and delivery

It is necessary to distinguish between research and development. While EVM is involved in a long-term research agenda, (FluSafe project) a pandemic flu preparedness plan should be based on current know-how and technology, which has been developed by industry over many years, in contrast with the more speculative malaria model proposed in the Commission document where vaccines are currently only in the proof of concept phases.

Vaccine development of the prototype vaccine is already being undertaken by industry (mock-up dossier), although these activities vary from company to company. This is the real cornerstone of the influenza pandemic vaccine development programme. Candidate pandemic vaccines filings for registration are expected in the coming months, and incentives have to be put in place.

Indeed, it should be noted that the principle of the EMEA guidelines is to produce a prototype vaccine (mock-up file) with a single strain (most likely candidate pandemic strain is H5N1) to allow an abbreviated filing registration procedure once the pandemic is declared and the final strain is identified by WHO and confirmed by EMEA. Thus, there is no need to submit a mock-up file for each possible pandemic strain, as described in the Commission document on page 5.

Concerning the manufacturing of the pandemic vaccines, the annual production of flu vaccines within a limited timeframe, illustrates industry expertise and know-how in producing safe and effective vaccines.

The role of the Public Health Institutes should be to prepare a library of potential pandemic seeds in coordination with WHO Reference Centres to ensure timely delivery of an appropriate viral "pandemic" strain to industry for the development and manufacturing of a pandemic vaccine. There is also a great value to be derived from support for serological and animal testing. In addition, EVM members could be interested on "ad hoc" support from the Public Health Institutes.

EVM proposes that the "PPP" document should contain the following structure and key elements:

1. Vaccine development

As mentioned already, industry has the technical expertise and the infrastructure to develop the pandemic flu vaccine, should the correct financial framework be available. The cost implication of the development of the prototype vaccine includes all the following elements:

- Adaptation of manufacturing area to produce Genetically Modified Organisms –GMOs- (validation procedures and decontamination SOPs against avian flu virus, protection of workers during the manipulation of an avian virus) .
- Preparation of specific master and working seeds of the virus for manufacturing.
- Manufacturing of monovalent batches and clinical lots at pilot scale.
- Development of monovalent formulation specific to a pandemic vaccine (current vaccine being trivalent)
- Toxicological tests on animals
- Clinical studies, including evaluation of antigen concentration, use of adjuvants and dose regimes.
- Regulatory activities (Common Technical Development –CTD-, documentation for clinical study….)

Despite the absence of financial support at this point in time and the cost involved, vaccines companies are already addressing the flu pandemic as a serious and imminent public health threat that needs to be tackled urgently. This is why the companies have already started working on the development of a prototype vaccine, which may never be used/put on the market. Therefore, a financial framework is necessary to reward and allow individual companies to continue to make the necessary investments to develop the mock-up influenza pandemic vaccines.

The contribution of Public Health Institutes could indeed focus on setting up a library of candidate seed stocks. This should be in coordination with WHO/ NIBSC. The Public Health institutes support could also be considered with regard to establishing and performing relevant serological testing of serum samples from clinical studies. But, in this respect, they should work closely with EDQM (European Pharmacopoeia) in order to qualify these tests for regulatory purpose.

2. Production capacity and coverage.

2.1 Indirect support to build production capacity through increased coverage during inter-pandemic period. Indeed, this has been acknowledged in page 3 and 6 of the Commission document. EVM, however, is of the opinion that meeting higher vaccination coverage rate in currently recommended target populations in Europe will not be sufficient to achieve a level of vaccine usage during the inter-pandemic period that would allow adequate production capacity to meet a pandemic. Lowering the age of the universal recommendations appears a cost-effective option that should be pursued to meet the needs of a pandemic (see EVM presentation to DG SANCO on 27.01.2005).

2.2 National Advance Purchase Agreements (NAPAs) will be considered by EVM as a firm commitment on behalf of individual Member States towards pandemic preparedness planning and, as such, should be included in the national preparedness plans. NAPAs should be encouraged by the European Commission. It is expected that when all member states plans and pandemic needs are evaluated, this will exceed total production capacity. Hence, it is imperative that member states commit to increasing coverage during inter-pandemic period with a view to increasing production capacity. Thus, setting NAPAs in all MSs would help to achieve equitable distribution by matching capacity with total pandemic demand. There is a crucial need, however, for national plans, and NAPAs, and relevant uptake coverage, to be coordinated and evaluated by the Commission on behalf of the EU. This will ensure that short falls in one member state are supplied from another with capacity. In this respect, it would be useful to establish a scorecard of member states' preparations.

We believe that a "central advance purchase scheme", as mentioned in the document page 15, could run the risk of being counter-productive to member states' efforts to engage in advance purchase agreements and in increasing national coverage rates during inter-pandemic periods. A "complementary" APA should be considered once the 25th exists. The EU's added value should be to expand the populations covered in each member state.

3. Equitable distribution of pandemic vaccines

The EU's critical role should be to secure equitable supply through an EU legal framework/instrument to guarantee free export from producing to non-producing countries to respect the NAPAs. In addition, the threat of member states closing their borders in a pandemic can be avoided if agreements can be executed which succeed in increasing production capacity to match total vaccine needs.

Other considerations

EVM understands that the proposed "PPP", described in the Commission document, will only cover EU market needs. We also should bear in mind that half of European production is currently exported to markets outside the EU, and represents almost the totality of influenza vaccines distributed outside North America, Japan and Australia.. EVM would like to understand the Commission views on how to accommodate the needs of neighbouring and developing countries regarding flu pandemic vaccines.