

European Vaccine Manufacturers¹ -EVM- comments on the Commission Green paper on bio-preparedness

EVM considers that the Commission Green Paper raises important points, and EVM would like to propose some suggestions regarding two of them.

1) On Security standards in research and production facilities **(Question 9, 10,11, 15, 21, 25)**

EVM recognises the importance of security standards in this field:

- EVM member companies comply with applicable European and national safety and security legislation and regulatory requirements.
- EVM supports established ethical and professional standards in the research, development, manufacture and distribution of its products.
- EVM member companies have internal guidelines that go beyond the legislative requirements. These standards are found in, but are not limited to, the following:
 - Good Manufacturing Practices (GMP) standards
 - Bio Safety laboratory requirements
 - All-Hazard plans and guidelines
 - Environment, Health and Safety guidelines and SOPs

EVM understands that compliancy represents additional costs for companies but considers that all stakeholders should apply to minimum bio-standards and encourages the Commission to promote the exchange of best practices at EU level.

However, any additional requirement should:

- Not go beyond what is necessary to maintain security and safety of biomedical research.
- Find an optimal balance between security and safety of biomedical research, without unduly hampering scientific progress in the field of bio-preparedness (i.e., medical counter-measures against the bio-threats in question).
- Keep in mind that the level of risk of research / production activities vary by Bio Safety level, which is already reflected in national and EU legislation.

EVM would welcome being a partner in future policy developments in this field.

¹ *EVM members companies are major suppliers of vaccines worldwide, producing around 80% of vaccines used in the world. EVM members are: Baxter, Berna (Crucell), GlaxoSmithKline Biologicals, Novartis Vaccines, Sanofi Pasteur, Sanofi Pasteur MSD, Solvay Pharmaceuticals, and Wyeth*

2) **On defence mechanisms, medical countermeasures and other provisions during health emergencies**

Question 2, 6,8, 20, 21, 27, 33, 34, 35

EVM considers that the EU could play a coordination role in Bio-preparedness, as bio-threats transcend national borders and EU Member States heavily depend on each other's performances in a bio-preparedness strategy. Given the strong spill over of national Biopreparedness, coordination could be beneficial in different areas such as:

a) **Access to medical countermeasures**

EVM strongly believes that any preparedness planning needs to include planning and access to medical countermeasures during emergencies.

EVM recommends that this approach should comprise:

- **Science-based stockpiling policies against key pathogens** such as pandemic influenza or smallpox that have international support and are covered by WHO guidance recommending the development of national and global stockpiles.
- **Pro-active and complementary research policy**, that will allow developing, testing and disseminating innovative technologies required for delivering tailored medical countermeasures in real-time. EVM supports the initiative of the European Commission to develop a "European list of pathogens", which includes an assessment of technologies available to respond to such disease agents taking into account the list EMEA has developed, together with the Commission and industry. ²

b) **Other mechanisms**

EVM considers that there are other mechanisms that are useful to enhance preparedness such as:

- **A redesign of existing European Solidarity Fund**. The European Solidarity Fund could be revised and widened to also cover biosecurity related crisis. For example, widening the scope of the ESF and reviewing its mechanisms to also cover influenza pandemic could boost preparedness in this field.
- **To promote Public-private partnership (PPP)**, which is a system where a government service or private business venture is funded and operated through a partnership of government and one or more private sector companies. EVM would support the development of Public Private Partnerships (PPP) as long as the conditions of a true PPP are met including push and pull elements, where all parties deliver according to their expertise in mutual respect.

² EMEA website <http://www.emea.europa.eu/htms/human/bioterror/bioterror.htm>