

# Alliance for Biosecurity

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*Via E-Mail*

European Commission  
Bio-preparedness Consultation  
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1049 Brussels, Belgium  
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Re: Alliance for Biosecurity Comments on Green Paper on Bio-Preparedness

Dear Commission Staff,

The Alliance for Biosecurity welcomed the preparation of the European Commission's Green Paper on Bio-preparedness, and we appreciate this opportunity to submit comments. The Alliance for Biosecurity is a collaboration between the Center for Biosecurity of the University of Pittsburgh Medical Center and leading biotechnology and pharmaceutical companies, many of which conduct business in the European Union and some of which are headquartered here. Membership and mission of the Alliance are described in Attachment A.

The Alliance was founded on the belief that government and industry can most effectively and efficiently prepare for 21<sup>st</sup> century bio-threats by working in close partnership together. In the United States, the Alliance has been deeply involved in contributing to a public dialogue on a range of significant biosecurity issues. The group operates as a resource for extensive background on biodefense industry issues, and it has developed and communicated numerous policy proposals to the US Congress, the White House, the Food and Drug Administration, and the US Department of Health and Human Services (HHS). Public correspondence and testimony of the Alliance can be found at [www.allianceforbiosecurity.org](http://www.allianceforbiosecurity.org).

Most recently, members of the Alliance have begun to assess the possibilities for and barriers to expansion of international bio-preparedness efforts. Alliance members are very interested in engaging with the European Commission and individual Member States on the many issues identified in the Green Paper. We encourage the Commission to continue its work on bio-preparedness, and we suggest in particular that the Commission host public workshops on the topic to raise awareness and facilitate consensus building in this very complex policy area. The Alliance also recommends that the Commission look for opportunities to engage in regular communications with relevant US governmental entities, such as HHS, in order to better understand "lessons learned" from the US experience. Ultimately, an infectious disease pandemic or a bioterror attack, will have an international impact and could require unprecedented levels of communication and coordination between countries.

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DOR BioPharma, Inc. • DynPort Vaccine Company LLC, a CSC Company • Elusys Therapeutics, Inc.  
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NanoViricides • Pfizer Inc. • PharmAthene**

## Alliance Comments on EU Green Paper

One of the cornerstones of preparedness for a biological attack or pandemic is the availability of vaccines and therapeutics (*i.e.* medical countermeasures) to treat the impacted population. Because of the complex and costly nature of medical countermeasure development, the current capacity of most countries to respond to a sudden demand for life-saving countermeasures is extremely limited, and in some countries, almost nonexistent. An affirmative government *mandate* to acquire medical countermeasures and build technical capabilities is necessary because there is no natural commercial market demand for most of the countermeasures effective against bio-threats. It is the general sense of Alliance members that the main barrier to bio-preparedness efforts in the EU is the uneven threat perception and subsequent lack of policy decisions to purchase medical countermeasures.

While the US has a focused effort underway to acquire medical countermeasures for a US stockpile, neither its current stockpile nor its planned future stockpile will likely be able to satisfy other countries' potential needs for medical countermeasures during a time of crisis. A coordinated and focused national or regional imperative in the European Union will greatly enhance efforts to prepare in a timely way with effective defenses and a plan to deploy them. Other initial recommendations are outlined below.

### Public-Private Partnership

Since the "market" for medical countermeasures will need to be created by government, a close public-private partnership with committed participation from government, industry, and others is needed if countries are to advance medical countermeasure research, development and procurement. A collective call to action, increased communication and coordination, clear expectations, transparency, and a commitment to develop medical countermeasures are indispensable components of a bio-preparedness partnership.

A good first step towards establishing such a partnership in the European Union could involve a concerted effort by government(s) and industry to engage in initial discussions about available biodefense technologies, perhaps in a series of biodefense "industry days". It would also be useful for companies to have a general sense about which Member States have a potential interest in acquiring countermeasures intended for civilian use. Presently, it is a challenge for companies to identify the relevant agencies in various European countries that want to learn more about industry initiatives in the biodefense area. The Commission would do a great service by helping to sponsor initial gatherings for information exchange. Opening lines of regular communication between government, industry, and other stakeholders could reinforce the bio-preparedness partnership in Europe.

### Role of Industry

The participation of both the biotech and pharmaceutical industries in medical countermeasure development is more likely to lead to the successful and timely procurement of medicines and vaccines than if only one of these industry groups is involved. Small and mid-sized biotech companies are often adept at discovering platform technologies and novel drugs. However, biotechs generally have limited access to capital and less experience in advanced development and production of products. Large pharma companies typically have more

research and development resources, are more familiar with regulatory processes, have experience with moving products through development to licensure, and have the capacity and infrastructure to produce large quantities of medicines and vaccines. However, the opportunity costs of medical countermeasure development are higher for big pharma, and the liability risks are also greater. While the dynamic involvement of industry is needed to bolster bio-preparedness, the countermeasure development area is seen by most companies as risky, cumbersome and uncertain from a regulatory perspective, and highly speculative financially. Government and industry must think of creative ways to steer industry's capabilities and energy to this critical area.

It will be especially important for industry to jointly explore alternative, innovative ways to streamline and transform traditional research and development models, thereby decreasing costs and timelines currently required for R&D. It should be a goal to radically accelerate medical countermeasure discovery, development and production to improve countries' abilities to defend against unanticipated, bioengineered threats and to treat a broad spectrum of new and re-emerging infectious disease threats. The Alliance is engaged in an analysis of how best to accomplish this goal, and we would be interested in learning European perspectives and policy suggestions in this area.

#### Role of Government

In order to create a stable and effective market for medical countermeasures, the government should, to the maximum extent possible:

- § Establish a clear point of authority and accountability for bio-preparedness in each country or region. Bio-preparedness will require unprecedented coordination between different parts of government, including agencies or departments responsible for health, military defense, intelligence, and emergency preparedness. It is extremely useful to have a central point of government leadership with clear authority and resources to take ultimate responsibility for a nation's or region's biodefense.
- § Appreciate that drug discovery, research and development is a time-consuming (upwards of 10 to 12 years), risky (high failure rates), and costly (several hundred million dollars per product) endeavor. No drugs or vaccines, including medical countermeasures, can be produced overnight, or even within a year's time. This is a difficult reality that must be recognized. Progress towards increased bio-preparedness can only come about if government is able to contribute adequate levels of funding and tolerate sufficient levels of risk and failure.
- § Define the minimum market for each countermeasure or technology. Companies – and their investors – will respond best if government clearly articulates the types and specific amounts of medicines, vaccines, and/or technology platforms that it intends to acquire as early as possible in the process. Understandably, government predictions of needs will not always be accurate. But striving for predictability will greatly motivate industry to participate in countermeasure development.
- § Maintain a transparent process. The process developed by countries to determine medical countermeasure needs, fund product development and acquire

countermeasures should have clear timelines and deliverables throughout the research, development, and procurement process.

- § Set predictable rules for the treatment of intellectual property rights. It is critical to establish fair and unambiguous guidelines for the treatment of companies' intellectual property rights in the event of a public health emergency requiring the use of medical countermeasures. Intellectual property protection is essential for industry innovation.

The Alliance agrees with the Green Paper's conclusion that "The challenge of today's bio-threats requires advance planning and a long-term policy approach." There are many workable approaches to developing a functional national, regional, or international bio-preparedness effort. The Alliance would welcome an exchange with the Commission and the Member States about a way forward in Europe.

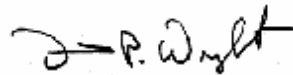
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The Alliance for Biosecurity greatly appreciates this opportunity to submit these comments to the European Commission, and we look forward to engaging in a continued dialogue on this issue in the future.

Respectfully submitted on behalf of the Alliance,



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