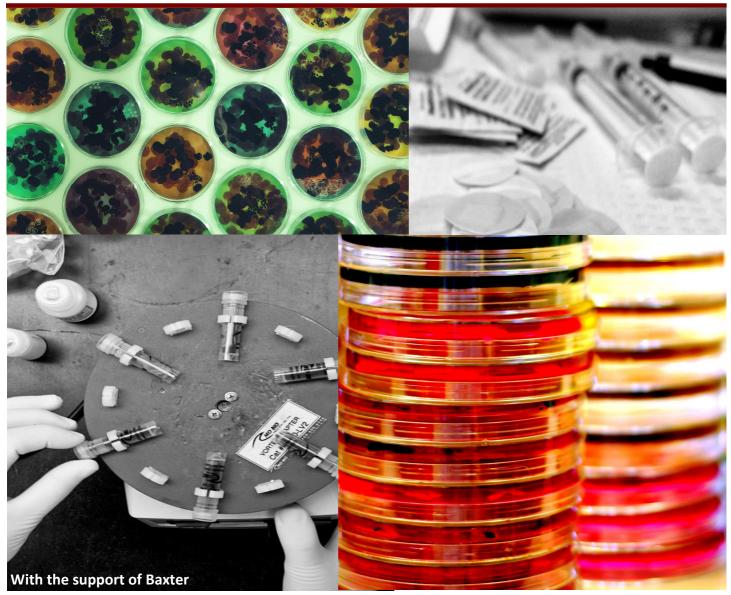


**SDA Report** 

# Charting improvements in European health security

November 2012



**SECURITY & DEFENCE AGENDA** 

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**Policymakers' dinner** Thursday 29 November 2012 Sofitel Brussels Europe



The EU health security package proposed in December 2011 by the European Commission will, if approved by the Council of the European Union and the European Parliament, create the legal basis for addressing serious cross-border health threats and strengthening the role of the Health Security Committee. The legislative package also includes a proposal for the joint procurement of medical count measures at European level. Improved cooperation and coordination between national health and emergency services is clearly an important goal, but so too is improving the general level of preparedness and resilience in the event of a 'flu pandemic or a deliberate terrorist attack such as a smallpox release. Where is EU-level policymaking headed on these threats, and how successful does the Commission appear to be in rallying national governments to a common health policy? While the H1N1 episode has improved communication between Europe's national and even regional authorities, what progress has been made on European vaccine production and stockpiling? How resilient – collectively and individually – are EU member countries to a serious outbreak of a communicable disease? Can we draw lessons from joint procurements in other areas?

SDA policymakers' dinners bring together some 25-30 senior stakeholders to raise the profile of key security and defence issues. The dinners take place in a prestigious yet informal environment with the SDA's Advisory Board and members.

#### **Speakers**



**Anne Glover** *Chief Scientific Advisor to President Barroso* European Commission



**Didier Houssin** *President* French Evaluation Agency for Research and Higher Education (AERES)



John F. Ryan Acting Director for Public Health Directorate General Health and Consumers European Commission

#### Moderator

**Giles Merritt** *Director* Security & Defence Agenda





Introduction

As the European Parliament prepares to approve the European Commission's package on serious crossborder threats to health, the SDA gathered together a distinguished group of experts in the field of health security to examine the package and discuss the future of European health security.

Introducing the debate, SDA Director **Giles Merritt** asked the fundamental question 'where is crossborder health security in Europe going?'. Stating that although there have been improvements in the intervening ten years, there was, he said, a feeling that Europe was relying on luck, and that "the security of European citizens can't be left to hoping for the best." Debating Europe's preparedness for future crises, participants disagreed on Europe's level of readiness and preparedness, but the general conclusion was that Europe holds great potential for managing health risks and with joint purchasing and stock-piling of vaccines, effective cross-border coordination and effective communication with the citizens of Europe, success can be achieved.

# The challenge of cross-border coordination and risk management

**Anne Glover**, Chief Scientific Advisor to President Barroso, felt that although Europe is extremely competent at assessing risk, she is not convinced that we are so good at managing it.

She asked the question "can we not make it easier for member states to coordinate not only with each other, but with the private sector?", as stimulating cross-border and industry coordination would aid in risk management and resilience. Other health issues which may not usually be looked at as threats to health security need to be considered. For example,

illustrated Glover, if a person becomes ill with cancer, they expect to be able to go to hospital to be treated

"We're really not as prepared as we could be"

accordingly, often by chemotherapy. Yet people are not aware that in Europe, one of the reactors, which produces seventy per cent of the radioisotopes used in health care for diagnosis or treatment, is over fifty years old and a timely replacement is not ensured. If the patient needs a radioisotope for health, it has to get from the point of synthesis to the hospital that's going to use it as quickly as possible, because the half-life of the most commonly used radioisotope, Technetium-99m, is six hours. "There needs to be a geographic spread in the European Union of reactors which are fit for purpose in producing radioisotopes for medical health, and we are not even looking at this", she said. "Our resilience in this area needs to be addressed."

Responding to Merritt's question as to whether Europe is prepared for a pandemic, Glover said "we're really not as prepared as we could be". Being in a European union provides the "perfect environment" for coordination of cross-border activity, "yet that's simply what we don't do". This is a big problem when it comes to resilience, particularly against some important infectious viruses, she continued, as there are currently only eight EU member states



"risk management requires a

very sophisticated

understanding of what is going

on"

that have category bio-safety level 4 labs that are equipped to handle such viruses. **Roberto Bertollini**, Chief Scientist and WHO Representative to the EU, agreed with Glover's opinion on risk management. "There are objective difficulties in making some decisions, and in other cases uncertainty around what is the best approach", he said, adding that "risk management issues require a very sophisticated understanding of what is going on, good learning from

past experience and evaluation of what has been done in the past".

Improved public-private cooperation and the integration of new technologies into daily life, in a way that is acceptable to the citi-

zen, would go a long way toward helping Europe manage risk better, as would improved communication with Europe's citizens. Lack of effective communication with the citizen is "often a cause for complete failure in attempting to introduce new technologies or approaches", explained Glover. Europe doesn't make the effort to speak to people in a language they understand, and yet unless the citizen is informed and empowered the Commission will not be able to make relevant decisions on health security as it is the citizen that empowers that politician. For Glover, this is the biggest challenge facing European health security.

However, John F. Ryan, Acting Director for Public Health in the European Commission's DG Health and Consumers, stated that Europe is more prepared than people might otherwise believe. Whilst the Health Security initiative is intended to reinforce European response to serious cross-border threats to health, Europe is "not starting from scratch" in this area. There has been a legal regime in place for communicable diseases since the late-1990s at European level; over fifty diseases and conditions are under obligatory surveillance; and member states are obliged to inform each other of outbreaks and meet together in a formal committee to discuss the appro-

> priate responses to these outbreaks. The Health Security Initiative will extend this existing system to cover other types of serious cross-border threats to health, particularly those resulting from deliberate release of biologi-

cal agents, and also chemical, environmental and unknown threats.

Based on lessons learnt from previous pandemics, such as the H1N1 pandemic and the E. coli event of 2011, the Health Security Initiative has received the full support of both the European Parliament and the Council. Once approved, preparedness will be enhanced as rather than a single preparedness plan at European level, every Member State will be obliged to have national plans, which will be compared by the Commission to ascertain weak-points and gaps.

The risk assessment mechanism for communicable diseases will be extended to other threats, through the establishment of a system involving independent experts in different threats areas that the Commis-



sion can call together at short notice to provide a risk assessment. Recently, experts were called together to produce a risk assessment following the discovery of large amounts of mustard gas in Libya.

In the area of risk management, Ryan felt that Europe will be much better able to manage risks once the currently informal health security committee is formalised to become the risk management committee for communicable diseases and for other types of threats. Regular exercises are also launched without any prior warning, to assess how long it takes key decision makers to react and to assess risk preparedness and management, continued Ryan.

However, there are areas of discord between the Council of the European Union and the Commission in relation to the health security package, primarily in how far member states want to go in a common approach in preparedness, and \_\_\_\_\_

in common measures, said "If member states say 'back off, we'll Ryan. do our own thing', that is a real

The Commission has proposed that if all else fails and an event –

that cannot be controlled at national level, the Commission will have the power, through delegated acts, to step in and adopt emergency measures. Member states are "unanimously nervous" about this, saying it must come out of the text, as it is seen as a loss of national sovereignty in this area.

This emphasised Glover's concerns about the lack of cross-border coordination amongst member states in this area. Transmission patterns have changed considerably in the past century, as borders begin to matter less and less - a modified organism or an infectious disease doesn't care about borders, and neither do people, so member states must learn to react to these threats in a different way and coordinate with each other as much as possible. "If member states say 'back off, we'll do our own thing', that is a real problem" she concluded.

#### The image and role of the pharmaceutical industry

Outlining the important role played by Europe in international health security through the ages,

**Didier Houssin**, President of the French Evaluation Agency for Research and Higher Education (AERES), stated that the health security package represents not just the strengthening of health security as an internal challenge for cohesion in Europe, but also the strengthening of health security as a European

global responsibility.

A key cause for concern is the public's perception of the pharmaceutical industry, he went

on. The lack of public trust in the industry needs to be improved, and Houssin proposed the formation of public-private partnerships in which industry, EU and WHO representatives would gather regularly in a setting that should avoid any suspicion of conflict of interest to "set priorities for medical countermeasures, defining what could be and could not be mutualised at European level, considering economical constraints and the need for secrecy in some

problem."



"The pharmaceutical industry...

together with public research

carries our hopes for future

progress."

cases, and to look for the most efficient mechanisms to secure supply of medical products, through acquisition stockpiling and for support to non-EU countries through the WHO." A specific European R&D authority should be created, he continued, within the framework of the Horizon 2020, taking lessons from the U.S.' Biomedical Advanced Research and Development Authority (BARDA).

These measures, along with a specific communication policy through which public authorities in Europe could support the image of the medical products industry, would be of immense benefit to European health security.

Whilst the driving force of the industry may be economic, improvement of its image is of extreme importance. The industry is "based upon the competence of skilled health professionals, acting for the general interest with many efficient products, is a large employer in Europe, a significant donator internationally and together with public research carries our hopes for future progress" in the field of

health security, stressed Houssin.

**Toon Digneffe**, Director for Government Affairs and Public Policy at Baxter

Healthcare, agreed with this view, saying that European health security "will only be successful if all stakeholders are included in that process and agree on a project plan in terms of how we can make people world-wide better prepared for a future pandemic" in a true public-private partnership. In such a setting, the industry could show what it can do for general preparedness world-wide. Discussions on creating such an efficient mechanism should be held.

Although Glover agreed that a true public-private partnership would be of great benefit to European health security, the central problem in achieving this lies in the fact that the public do not place any trust in the pharmaceutical industry, she said. **Leon Prop**,

# "There is a credibility deficit for the industry, and often for public authorities"

Director of the Red Cross EU Office concurred, saying "there is a credibility deficit for the industry, and often for public authorities. "

Continuing, **Michael Kunze**, Head of the Institute for Social Medicine at the Medical University of Vienna, stated that there is an on-going "public health cyberwar" against vaccines.

> Agreeing with this point, **Daniel Kenny**, Global Franchise Head of Vaccines at Baxter Healthcare, explained that in his experience, the industry has "almost given up" on trying to work out how to get the

public to trust the industry and their products. Despite rigorous testing, millions of dollars spent on research, registration with authorities and approval by independent regulatory bodies such as the European Medicines Agency and the U.S. Food and Drug



Administration, the public remains sceptical.

The uptake of flu vaccines continues to be a problem, said **Magdalena Rodriguez de Azero**, Executive Director at European Vaccine Manufacturers, yet this is essential to preparedness, and most member states have failed to accomplish the recommend uptake.

States also need to be more pro-active in their approach to vaccine stockpiling. Since the end of the 2009 H1N1 pandemic, many states have failed to reactivate concrete stockpiling of vaccines or create concrete advance purchase agreements. Whilst there are many tasks to be undertaken in the event of a pandemic, Kenny elaborated, citizens need to be vaccinated, and should a pandemic occur six months from now, there would be a "scramble" between member states to obtain vaccines. Europe is a hub for vaccination research, yet it is the United States, through the Biomedical Advanced Research and Development Authority (BARDA), that is taking advantage of this technology and utilising it rather than Europe. From an industry perspective, he said, "we are basically in the same place we were back in 2009."

## "we are basically in the same place we were back in 2009."

Responding to this concern, Ryan detailed the Health Security Initiative for joint procurement of vaccines and other medical counter-measures, envisioned primarily as a result of the competition for vaccines amongst member states during the 2009 H1N1 pandemic. This initiative will make it easier for member states to procure vaccines together in the event of a crisis.

#### Communication - a key challenge

All participants agreed that communication with citizens is an area that necessitates further improvement, to enhance not only trust in the industry but to improve health security more broadly. Kunze stated that generally, citizens underestimate large risks, such as tobacco, and overestimate small risks. The effect of media on perceptions and reactions to crises can be extremely influential. It is thus important that the relevant authorities communicate to the citizen as much as possible before and during an event. "People will react better and be able to protect themselves much better" if information is given to them, said Glover, so it is imperative that citizens are put in a position where they want to help themselves and are able to help themselves. Involving and informing the citizen will not only help them protect themselves, but strengthen Europe's resilience to cross-border health threats.

In the experience of the Red Cross, added Prop, providing the citizen with simple messages is crucial – during the H1N1 pandemic, resilience was built by telling citizens "the best defence is you". Health risks and security measures should be discussed and debated openly and understanding of risks should be incorporated into public education, as trust can-



"There is tremendous potential in

harnessing social media"

not be built or gained in the middle of a crisis. The groundwork must be laid before.

The European Commission response to communication issues was proffered by Ryan. A network of communicators was created following the H1N1 pandemic, which analyses the information coming from risk managers in the event of a crisis, develops a communication strategy based on that, and communicates to the press.

With participants in agreement as to the necessity for effective communication, concerns were raised about the role of social media and whether it is a force for good or bad during a crisis. Bertollini added that social media makes communication with citizens more complicated, and needs to be looked at more. However, Prop felt that "there is tremendous potential in harnessing social media". Two-way communication with citizens through social media is beneficial to both parties, whereas communication

from the authorities to the media is only a tiny percentage of the necessary communication, and is not \_

effective enough. It is a "fallacy" to believe that the Commission could survey social media, as it doesn't have the resources, said Ryan, and social media can have negative effects, particularly in the area of vaccination of children.

A final issue raised was the possible impact of environmental threats on European health security, with Glover describing the threat of space weather. "We are very good at predicting our own weather, yet not so good at predicting space weather", she asserted. Changes in space could lead to failure in power supplies and navigation systems, with potentially devastating effect. More time needs to be spent on researching this phenomenon, she said, as it is not a matter of if it will happen, but when.

Ryan agreed that space weather was very interesting and informed participants that it has been drawn to the European Commission's attention and certainly warrants further investigation, but added that we do not need to look as far as space to find serious environmental threats.

The Icelandic volcano eruption of 2010 was one unforeseen environmental event which had important health and economic consequences throughout Europe, breaking the pharmaceutical supply chain and affecting organ transplants. Likewise, the E. coli incident in 2011 had major economic and health consequences, with German hospitals full, European exports blocked for three to four months and an 800 million Euro impact on the Common Agricultural Policy Fund.

> - Minds must be opened to trans-boundary issues such as climate change, said Bertollini, noting that climate

change can have security implications for infrastructure and health, and can create conditions in which the transmission of viruses and infectious diseases is favoured.All participants agreed that climate change is a threat to European health security, though the problem in this case is that whilst we know what needs to be done, we are not doing it, cautioned Glover.

The issue of funding and the impact of austerity budgets on health security then came to the fore. A lack of institutional learning from past events, combined with austerity measures, will conspire to reduce preparedness, said Kenny, whilst **Line** 



Matthiessen-Guyader, Head of Unit for Infectious Diseases and Public Health at the European Commission's DG Research and Innovation, pointed out that given budget cuts, we need to learn to better utilise the resources we already have. Biosecurity must not be endangered by austerity, she added, emphasising that states must encourage and invest in the training of scientists on these issues and check that all publicly funded projects are complying with national rules, as "zero risk does not exist".

#### Conclusion

As the evening drew to a close, it was clear that the Commission's initiative does not represent the end of the discussion. Once the health security package is approved by the European Parliament, Europe will embark on the next stage of the discussion, in which it must ensure that not only do member states have a collective security from disease, manmade and natural disasters, but must lead the way on global health security. Not all non-EU states are as prepared to face threats, nor are many communicating with EU member states upon discovering a threat. The EU model represents an important formula for creating a much more global health security regime.

Whilst the health security package will go a long way in improving Europe's preparedness for and response to serious cross-border threats to health, EU member states must coordinate with each other if the package is to provide the protection envisioned by the Commission.

However, the health security package can only go so far. The participants were in agreement that effective communication not only with citizens but amongst the pharmaceutical and medical products industry, EU and government authorities, and international organisations is central to ensuring European health security. Only when all sectors of society cooperate can Europe be protected from crossborder threats to health.



**SECURITY & DEFENCE AGENDA** 

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