

Medical Countermeasures



Medical Countermeasures: Challenging the Status Quo

By Mark Johnson



The medical countermeasures (MCMs) chapter of the *CBRNe World Directory 2013* included a focus on the history of MCMs, required market characteristics to stimulate its availability, and various positions of international institutions and public figureheads concerning the need for relevant CBR (chemical, biological, radiological) MCM preparedness plans. Consequently, it became evident there would be a need for cooperation between government and industry. Since then, a hearty observance has been dedicated toward perceiving changes in international (non-US) CBR policy as well as related actionable behaviour towards developing innovative MCMs.

One thing appears indisputable: Key relevant international institutions (eg the European Commission, United Nations, Nato, OPCW, Interpol) clearly and publically acknowledge that CBR weapons of mass destruction (WMD) pose a threat to society. While the level of this threat perception remains less transparent, the pragmatic will to prevent such threats from happening does emerge. Nonetheless, it need not be said that the overall task to prevent all attempts of intentional WMD use (nonetheless respond to a CBR event if it happens anyway) is not only expensive and time consuming, but it is also an extremely complex and non-harmonious endeavour. This is because, while the challenge requires coordinated process flow throughout various international institutions, governments, scientific and industrial bases, there are seemingly countless stones which must be unturned. Just to name a few, there are a number of threats, synchronization of diverse expertise, conflicting priorities and interests, and multifaceted pillars such as prevention, response, and decontamination. Particularly for MCMs where clarity of market characteristics (product definition, market predictability, regulatory environment, and funding mechanisms) is not given in the absence of government initiation and financial commitment, yet another challenge is exposed. Namely, if the WMD threat level truly justifies robust preparedness plans, an effective response to such events is severely diluted if relevant and innovative MCMs are not immediately accessible at the time and place of need. Accordingly, governments and institutions become heir to the extra burden of not only cooperating effectively with industry, the developers and manufacturers of MCMs, but also to do so well in advance given extensive development and manufacturing periods.

If the current scenario were such that the threat level vigorously commanded international MCM preparedness and response urgency which was noticeably reflected by mature CBR policy and relevant long-term budgeting, then it is more than certain that significant and well-defined market demand for MCMs would transpire. Thus, industrial effort would likely flourish to identify, develop, and manufacture in accordance. Especially if it were perceived that non-state actors, terrorists, seriously threatened society by striving to use the power of modern medicine in a negative way, it is plausible that many international governmental entities (eg Ministry of Health) would seek to win this race by creating large strategic national stockpiles of innovative MCMs with the purpose of enabling a healthy medical response in such an event. As is well-known, such a model has been pioneered by the United States (eg BARDA to support MCM development and the Strategic National Stockpile to set market sales potential via transparent procurement contracts). However, with the threat remaining ambiguous in most other countries and responsible preparedness plans complex and costly, it is conceivable that a few countries will be left alone to 'carry the load' while most other government forces and entities continue to rely exclusively on the prevention of such WMD events. Consequently, procrastination of an international preparedness and response plan is likely to prevail. After all, how many government officials are willing to dedicate themselves to stimulating development of MCMs such as vaccines and antivirals where history has demonstrated that achieving success even in the long-term is very risky? What's more, such MCMs are commonly perceived by society to be precious life-saving miracle drugs only when the disease it targets against begins to actively kill in a large and terrifying way. Until then, politically speaking, such preparedness spending can easily be categorized as a waste of taxpayers' money and the work of 'those' lobbyists. This is obviously not a politically sexy topic which can gain votes for those seeking short-term benefits during election periods. Besides, in the movies, a novel drug is always found just in time to save the entire world and bring about a happy end.





But what if a major WMD event does happen and a comprehensive, full-force, and innovative medical response becomes critically essential? This scenario would not be compatible with the priorities set forth by most governments till now in terms of their ability to provide plentiful and effective MCM response capability. Do developed countries continue to believe that these things can happen only to others (such as the Syrian nerve agent sarin attack in August 2013)? During a real event, would the general public and political opposition – the same persons possibly opposing CBR readiness now – then accuse governing bodies of not having done enough to protect its citizens? If there is any light at the end of the tunnel, perhaps it could reveal that current priorities concerning new and innovative MCM preparedness plans are at least under discussion. Assuming so, an approach to enable both industry and governments to avoid the valley of death in terms of return on investment will be explored later, but first it may be interesting to summarize CBR policy development which sheds enough bureaucracy to allow a blip of hope to escape and appear on the industry radar screen.

Seemingly at the helm of driving policy matter, it would appear the role of the United Nations (UN) under its resolution 1540 sparks and drives an international collaborating force. A few years back, conversations with UN officials tended to reflect an exclusive dedication to the prevention of WMD events achieved through the nonproliferation of WMDs. However, language can be found in their documentation which includes the need for MCMs within the context of response capabilities in case a WMD event does happen. For example, the UN Biological Weapons Convention (BWC) openly represents a spectrum of biological risks and differentiates its responsibilities from that of the World Health Organization (WHO). While the WHO is mandated for natural disease outbreak as well as unintended consequences, the BWC has been allocated the areas of vandalism and the deliberate use of biological weapons. Both organizations share the mandate in the areas of accidents and negligence within this spectrum. Further evidence signifies the BWC's mission to encourage cooperation for dealing with international MCM preparedness and response issues. For example, the final declaration of the BWC's Article X states:

Recognizing the fundamental importance of enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, the Conference agrees on the value of working together to promote capacity building in the fields of vaccine and drug production, disease surveillance, detection, diagnosis, and containment of infectious diseases as well as biological risk management. The Conference affirms that building such capacity would directly support the achievement of the objectives of the Convention.

Consequently, the UN appears to be a natural collaboration champion for the initiatives as set forth by the CBRN Center of Excellence (CoE) Network. Actually, this network joins collaboration of several organizations (eg the IAEA, OPCW, UNODA BWC-ISU, WHO, Interpol, Europol, UNSCR 1540 Committee).

The rationale for the CoE body is cited as:

While knowledge and expertise needed to mitigate CBRN risks of criminal, accidental or natural origin are available at national, regional and international levels, these resources are often not effectively implemented. Lack of coordination and preparedness at national levels and fragmentation of responsibilities within a region can have dramatic consequences: non-state actors trying to acquire CBRN materials or expertise will exploit this situation, and an incoherent response will broaden the impact of a CBRN incident. This is why the European Union is putting in place a framework providing for cooperation and coordination between all levels of government and international partners.

The EU Instrument for Stability which funds the EU CBRN Risk Mitigation CoE Initiative with the estimated amount of 95 million EUR for the 2007-2013 period is mobilising national, regional and international resources to develop a coherent CBRN policy at all levels, thereby aiming to ensure an effective response. The establishment of regional Centres of Excellence is a cornerstone of these activities: they offer a coherent and comprehensive approach covering legal, regulatory, enforcement and technical issues.

Particularly in Europe and specifically in the health area, the Directorate General for Health & Consumers of the European Commission (Sanco) announced its decision in July 2013 to strengthen health security in the EU in order to assure EU citizens that a robust and coordinated risk and crisis response is in place to protect them. In their memos 13/644-5, it is stated:

People in Europe will be better protected from a wide range of health threats through strengthened preparedness planning and coordination at EU level for serious cross border threats caused by communicable diseases, chemical, biological and environmental events. One of the key achievements of the Decision is that it establishes the legal basis for the coordination of voluntary joint procurement of vaccines and medicines at EU level.... The Decision also boosts the European Union's authority in the event of a health emergency: it allows the EU to declare a health emergency within its territory to trigger measures under its pharmaceutical legislation so that vaccines and medicines can be provided faster. The clear mandate for the Health Security Committee (HSC) to coordinate risk and crisis response, including communication, during a crisis, means that coordination of public health emergencies will be further improved.

Reasons for strengthening health security in Europe are paraphrased as:

Communicable diseases and health threats caused by chemical or biological agents, or environmental events do not respect borders.

Experience demonstrates that if one or several EU countries affected by a health crisis are not adequately prepared, any weaknesses will hamper the EU response capacity and negatively impact the situation in other Member States as the crisis spreads.

Threats to public health arising from chemical or environmental hazards have so far been treated on an informal basis.

Health threats legislation requires alignment with international developments (eg as during global health crises, there are clear links between EU level activities and those of international public health organizations).

Perhaps most significant in practical terms of European policy development is the change concerning the HSC. Since the anthrax letter attacks in the US back in 2001, the HSC was setup at the request of EU health ministers as an informal body. Since the end of 2013, it has been formalized for the coordination of public health measures dealing with serious cross-border threats to health in the EU.

While such policy measures seek international capacities for rapid and impactful response to health crisis, it also increases the need for governments to cooperate effectively and efficiently with industry. Since governments must actively entice industry to develop especially those MCMs which lack natural market characteristics, the roots of communication effectiveness between both parties warrant a brief visit. That is to say, in any situation there is always potential to enhance the quality of dialogue and boost results for all. Firstly, nothing is more frustrating than to see company representatives attend key government institutional meetings, but witness they have nothing to say or contribute. While industry must assure the expertise and personalities of their representatives can match those which are suitable for the meeting's purpose, government officials should more thoroughly safeguard an appropriate and comprehensive invitation list. Secondly, it is legitimate that company representatives are required to characterize their company interests; however, when defining and communicating market characteristics, expertise must be expressed neutrally and credibly. Once government officials can build trust with individuals from industry and better understand required market characteristics, only then can a market emerge. As soon as an adequate market is born, then the marketing and sales functions of individual companies can begin their fight against competitors for market share. Quite often, however, industry is not invited to government meetings (or merely tolerated) because they are easily perceived as 'only wanting to make profits'. While this perception is often and understandably associated with negativity and bias, it needs to be understood that 'profit' doesn't have to be a bad word. In fact, profit must flow through the veins of industry and provide for its existence. In truth, the pioneer of the western political economy and father of modern economics, Adam Smith, portrayed the constructive principles of market function in his invisible hand theory. Roughly illustrated here, yes, self-interest will drive risk-taking, innovation, and productivity; however, competition will keep the necessary checks and balances in place. In this sense, the motivation of profit has indeed driven economies to a level of prosperity which enables the basis for government, business, and society to run smoothly.

Given the aforementioned policy and dialogue characteristics, so now it's time for government and industry to sit down and initiate action to ensure the international availability of MCMs, right? Assuming a worthy threat level, at least it appears to be. That is, until a government official vomits the killer phrase which echoes down the public halls: 'It's too expensive.' Since governments do many things that are expensive, this can only be interpreted as an excuse that MCM response and preparedness simply lack priority. And/or is it a cry for help because it is a large and complex task which does not appear achievable? Where and how does one begin? To date, most MCM focus has been on vaccines and antivirals where risky and costly development can take up to 20 years. To enable a potentially easier access to entry in terms of at least initiating a development and procurement process, how about briefly turning attention to Point of Care (POC) medical testing devices that can rapidly diagnose human exposure to various CBR agents? While such POC testing devices might require considerably less time and risk to develop, they may also play a monumental role when it comes to minimizing health havoc presented during a WMD event. For example, in the event of a CBR attack, hospital capacities in most areas will not be sufficient for dealing with an unusual surge of patient flow. In addition to the number of those genuinely injured, there is likely to be a significantly higher population of healthy people who only fear they have been affected (the so-called 'worried-well' population). In fact, according to 'The "Worried Well" Response to CBRN Events: Analysis and Solutions' by Fred P Stone (Maxwell Air force Base), these 'worried well' events may comprise as many as 20 times the number of 'legitimate' patients. As outlined in a case study of the Aum attack with sarin gas which occurred in a Tokyo subway system in March 1995, 85% of the patient flow was represented by the 'worried well'. At times of a CBR event where priorities must be concentrated on the truly injured in order to minimize negative health consequences, POC testing devices can be ideal for supporting the process of mass screening; thus optimizing available resources and capacity for the injured.

But who's ready to initiate the task of protecting society from a wide range of CBR threats by creating a fertile platform to create new and innovative medicinal products such as vaccines and antivirals? Now, from those volunteers still standing and financially supported, who is willing to do so one to two decades before they are needed given their long development times – anybody? Like many challenges that are just too large and complex to begin, it becomes necessary to break up the problem into smaller 'doable'



pieces: To be achieved via allocation, delegation, and iteration. For example, if the international community could achieve consensus that CBR threat level justifies robust action to build a responsible preparedness plan which includes a wide range of new and innovative MCMs (eg POC testing devices, vaccines, and antivirals), then the task must be shared across the globe. One approach could be that a global network stems from several individual countries having its own 'US-esque' BARDA development and CDC procurement model within its borders. If several governments would transparently share and enact the vision to achieve a comprehensive MCM preparedness and response capability, then each of these countries could tackle a piece of the challenge and absorb its relevant costs (eg allocate agents to protect against, type of MCM, technology, commitment of market size to industry). Another approach could be that several countries across the globe create one vast base of CBR MCM industry players within one geographical area. While still achieving the global sharing of a global problem, a network of developers and manufacturers in close proximity, 'a cluster', may further enhance technological advancement; thus, increase chances of success. Based on Michael E Porter's cluster theory, *Harvard Business Review* describes that clusters foster high levels of productivity and innovation and lays out the implications for competitive strategy and economic policy. The most famous examples of clusters are found in Silicon Valley and Hollywood, but clusters dot the world's landscape. Clusters affect competition in three broad ways: First, by increasing the productivity of companies based in the area; second, by driving the direction and pace of innovation; and third, by stimulating the formation of new businesses within the cluster. Geographic, cultural, and institutional proximity provides companies with special access, closer relationships, better information, powerful incentives, and other advantages that are difficult to tap from a distance. The more complex, knowledge-based, and dynamic the world economy becomes, the more this is true. Competitive advantage lies increasingly in local things – knowledge, relationships, and motivation – that distant rivals cannot replicate.

Because financial investment of few countries has proven it can deploy only minimum industrial force, inactive governments cannot continue to leave others alone in their attempt to develop and procure innovative MCMs which may be vitally needed for stockpile inclusion. Whichever approach can be agreed by the global community and deemed most appropriate for best enabling such international preparedness and response capability, historical progress indicates that both government and industry must rethink its current methods. If CBR agents indeed pose major threats to our societies, the status quo of MCMs must be challenged. While it is perhaps human nature to wait until disaster strikes before urgency can drive change, only visionary and 'out-of-the-box' cooperation can lead to responsible CBR MCM preparedness and response plans before such an event takes place. Only then can the boiling frog metaphor be avoided – the frog jumping out of the pot before the water gets too hot. The effects of a robust international MCM plan could be two-fold: The international presence of a strong, innovative, and comprehensive MCM preparedness capability would not only reduce health hazard in the event of a CBR attack, but its existence alone may act as a disincentive for terrorists to pursue such goals in the first place. That is, if a race between 'good' and 'bad' use of medical science has indeed been triggered, then only a highly actionable and globally coordinated counteraction by allied member states can maintain par and/or thrust its protective technology to the forefront. Strong fronts can provide deterrence to an attack.