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Medical Countermeasure Product Development - Alternatives Paper

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Land Division
Defence Science and Technology Organisation

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ABSTRACT

Chemical Biological and Radiological (CBR) threats, emerging infectious diseases and pandemics pose an imminent, real and serious danger to Australia's healthcare system, its economy and national security. In order to respond and have an all-hazard preparedness approach to these threats, Medical Countermeasures (MedCMs) are required. MedCMs can include drugs, vaccines and diagnostics (devices and materials). Currently, there exists a dependence on non-Australian sources for MedCM products however there is no assurance that these products will be available in a time of need. Alternative solutions must be considered and developed. This paper provides a strategy focused on exploring affordable and integrated capability to acquire (by development or purchase) MedCM products for Australia.

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Executive Summary

The Medical Countermeasure (MedCM) Consortium is a four nation partnership involving the Defence and Health Departments of Australia, Canada, the United Kingdom and the United States. The Consortium seeks to develop MedCM including drugs, vaccines and diagnostics to assist with all-hazard preparedness and response. The emphasis of the Consortium is on Defence and Public Health-related issues such as Chemical, Biological and Radiological (CBR) threats affecting civilian and military populations and has been expanded to include emerging infectious diseases and pandemics.

To understand Australia's capabilities, both common and unique, which could provide beneficial programs and products to the Consortium, DSTO commissioned a National Survey entitled '*Mapping Australia's Product Development Capability for Medical Countermeasures, October 2013'*. The results of the survey were presented at the Annual Australian MedCM Consortium Steering Committee Meeting and led to the Chief Medical Officer requesting a paper outlining the options/alternatives in addressing national MedCM product development.

Until recently, there has been very little incentive for the biotechnology/medical technology community to focus on MedCM product development. This was because the focus of our national preparedness strategy was on surveillance and containment. With Australia geographically positioned as an important sentinel for infectious disease threats such as malaria, dengue, multi-drug resistant bacteria/viruses and highly pathogenic strains of influenza there has been a growing awareness that MedCMs should be included in Australia's preparedness arsenal.

For policy-makers, the greatest risk may be not having sufficient types and quantities of MedCMs when the situation demands. Given such high stakes, it is imperative that government fully understand the risks inherent in commercial drug or vaccine development. As a consequence, the government should support mechanisms that make the appropriate resourcing and management of such programs available to the national innovation system and advanced manufacture communities.

Developing and procuring MedCMs is a complex process that requires coordinated engagement across the state, territory and federal governments and with

countermeasure developers in private industry. To address these issues the following alternatives have been considered:

1. National MedCM Product Information and Procurement Service;
2. Tender for each required MedCM;
3. Emergency Acquisition of Capability;
4. Independent Organisation; and a
5. Public Private Partnership;

They explore affordable and integrated national capability to acquire MedCM products for Australia.

The Alternatives outlined above provide a mechanism to create and sustain opportunities for local businesses and it is likely that when developing an appropriate national '*MedCM product acquisition strategy*' the Alternatives will have elements which complement each other. This could be shaped into an effective program with global outreach.

Reference: Craig Rayner and David Lester October 2013, *Mapping Australia's Product Development Capability for Medical Countermeasures*, *Lester-Rayner Repor*t *to Defence Science and Technology Organisation, DSTO*, ITH&W Pty Ltd.

Authors

Felicia Pradera
Land Division

Felicia Pradera graduated from Murdoch University with a Bachelor of Science in 1998 and Honours from Melbourne University in 1999. In 2001 she received an European Union Scholarship and obtained a Doktor rer Naturwissenshcaften - Biotechnologie (PhD) from the Technical University of Berlin in 2006. In 2012 she received her Masters in Intellectual Property Law from Monash University. Her first postdoctoral position was a continuation of her PhD work at the Benjamin-Franklin Klinikum, Berlin working on the effects of interferon gamma on the extracellular matrix of growing and regressing tumors. In 2007, she returned to Australia to take up a position at Australian Aerospace and Defence Innovations Ltd (AADI) constructing and leading the company's Counterterrorism strategic plan which included activities with Chemical, Biological, Radiological and Nuclear (CBRN) participants from industry and academia. In 2008, she began training as a biotechnological Patent Attorney with Davies Collison Cave and in 2010 returned to work in defence at DSTO. Her first position at DSTO was as a Business Development Manager in the Business and Commercialisation Office (BCO). The role required that she was part of a specialist team providing business and intellectual property advice to DSTO S&T and Executive staff. As a result of work done to support the development of the Australian Medical Countermeasures (MedCM) Consortium at the BCO, she was seconded to Land Division in 2013 as the Projects Manager - Medical Countermeasures. During this time she has facilitated and led collaborative research activities in MedCM product development with international and national partners. She has also been responsible for the development of a new initiative Medical Countermeasure Products Australia (MCPA), a public-private partnership involving industry, academia and government.

Malcolm Alderton
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Malcolm Alderton graduated from Monash University with a Bachelor of Science with Honours in 1980 and a Doctorate of Philosophy (Immunology) in 1984. In 1994 he graduated with a Graduate Diploma of Education and Training from RMIT, and in 2000 he graduated with a Graduate Certificate in Management from Flinders University. In his first postdoctoral position with Biotechnology Australia he worked on the coccidiosis project at CSIRO Animal Health (Parkville). He moved to RMIT University in 1988 and worked as a Research Scientist and Lecturer before joining Aeronautical and Maritime Research Laboratory of the Defence Science and Technology Organisation (DSTO) in 1995 as a Research Scientist. In January 1997 he was promoted to Senior Research Scientist and in 1998 became a Principal Investigator in a research collaboration with Australian Membrane and Biotechnology Institute (AMBRI) Pty Ltd to develop the AMBRI ion channel switch (ICS) biosensor for defence applications. In July 2000 he became the Task Manager for Biomedical Defence Against Biological Warfare (BW) Agents. In March 2001 he started a 12 month sabbatical with the CSIRO Health Sciences and Nutrition Division in Parkville. In 2005 he became the manager of the DSTO National Security Task, and then in 2007 he left Biological Defence to be promoted to Principal Research Scientist (S&T Level 7) and become the Capability Leader for Individual Protection and Performance. In 2009 he returned to Biological Defence as the Head of the Biological Warfare Agents Detection and Countermeasures Group and Task Leader for the Corporate Enabling Research Program Bioterrorism Preparedness and the Defence Support Group Tasks (2009 – 2011). He held the position of the National Leader for Technical Panel 14 – Rapid Diagnostics – of The Technical Cooperation Program (TTCP), prior to becoming the national Science and Technology lead for the Medical Countermeasures Consortium in 2014. He also acted as the Chair of the HPPD Security Committee for 3 years and has been the HPPD representative on the Black Box Lecture Committee for 4 years.

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Acronyms

BSL	Biosafety Level
CBR	Chemical, Biological and Radiological
CMC	Chemistry, Manufacturing and Controls
CT	Communications Team
DC	Development committee
DMPK	Drug metabolism and pharmacokinetics
FDA	Food & Drug Administration
GMP	Good Manufacturing Practice
MedCM	Medical Countermeasure
PPP	Public–private partnership
R&D	Research and Development
SC	Steering Committee
SME	Small to Medium business entities
TRL	Technology Readiness Level
WHO	World Health Organisation
WMD	Weapons of Mass Destruction

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1. Introduction

1.1 Purpose

The purpose of this paper is to provide an overview of the Alternatives for a medical countermeasure (MedCM) product acquisition (by development or purchase) strategy for Australia. The paper sets out the Alternatives based on existing research as well as the concerns raised by stakeholders. It also highlights the current issues and solutions provided by each Alternative.

A key focus of this paper is on exploring options for an affordable and integrated national capability to acquire MedCM products for Australia. Some of the Alternatives presented have the potential to directly benefit small to medium businesses that would otherwise not have an appropriate mechanism to demonstrate their technology or develop a niche capability for national and international benefit.

The Alternatives are likely to be intertwined and may be considered holistically when determining an appropriate national MedCM product acquisition strategy.

1.2 Background

The MedCM Consortium is a four nation partnership involving the Defence and Health Departments of Australia, Canada, the United Kingdom and the United States. The Consortium seeks to develop MedCM including drugs, vaccines and diagnostics to assist with all-hazard preparedness and response. The emphasis of the Consortium is on Defence and Public Health-related issues such as Chemical, Biological and Radiological (CBR) threats affecting civilian and military populations and has been expanded to include emerging infectious diseases and pandemics.

DSTO commissioned a Report[1] which included a series of surveys and workshops to understanding Australia's capabilities, both common and unique, which could provide beneficial programs and products to the Consortium. During the initiative, a groundswell of enthusiasm was generated by relevant activities including initial mapping of Australian capabilities, high-level engagement with senior FDA officials, and a self-assembly of industry, academic, government and research institute stakeholders resulting in the establishment of a National Taskforce to create an Australian MedCM initiative.

It was clear from the Report that, within Australia, emerging infectious diseases are of the highest priority as they pose imminent, real and serious threats to our national security, economy and healthcare system. However, it is unclear whether a focused strategy or policy for the acquisition (by development or purchase) of MedCM products has been

[1] Craig Rayner and David Lester October 2013, *Mapping Australia's Product Development Capability for Medical Countermeasures*, *Lester-Rayner Report to Defence Science and Technology Organisation*, *DSTO*, ITH&W Pty Ltd.

implemented by the federal government. Currently, there clearly exists a dependence on non-Australian sources for MedCM products and there is no assurance that these products will be available in a time of need. Therefore, alternative solutions must be considered and developed.

Analysis of the national landscape provides evidence to suggest that whilst Australia lacks an ***integrated*** capability in developing and delivering MedCM products, there is a small, dispersed but highly experienced discovery and development community who could be persuaded by Government to align their activities with National priorities. This paper provides some Alternatives for Government to support and guide MedCM product acquisition for Australia.

1.3 The Medical Countermeasure Product Development Landscape

Australia has examples of pharmaceutical products that have been developed and even commercialised by the biotech/medtech community, but these are limited. Until recently, there has been little incentive for the community to focus on MedCM product development as it has not been considered an important aspect of our national preparedness for public health emergencies. The focus has always been on surveillance and containment. The recent H1N1 pandemic influenza highlighted deficiencies with the current preparedness plan, in particular the execution failure due to lack of product integration, and the failure of the product due to poor matching of the product to the planned deployment and associated target[2].

Australia is geographically positioned as an important sentinel for infectious disease threats. Recent increases in i) multi-drug resistant bacteria (NDM1) from India; ii) Class III/IV pathogens including Hendra and Nipah virus in North Australia and South East Asia; iii) mosquito borne tropical diseases including malaria and dengue and chikungunya; iv) emerging highly pathogenic strains of influenza from Indonesia; and v) emerging multi-drug resistant tuberculosis from Papua New Guinea has resulted in a growing awareness that MedCM products should be included in Australia's preparedness arsenal.

1.3.1 Development requirements

In any pharmaceutical company part of the product development strategy is to have a cross-functional development team. This ensures that the team is composed of people with varied levels of skills and experience brought together to accomplish a task (Figure 1).

MedCM product development will involve similar if not more complex expertise and facilities to achieve a fully approved product for either the national civilian or military stockpiles. The recent Report[3] has provided Defence and Public Health with a picture of

[2] **Note**: Industry perspective
[3] *Ibid at 1*

national capability and the additional product development requirements for MedCMs. Of particular note is that whilst modest in size, there exists representation of all the key components (people, products and facilities) necessary for Australia to be able to significantly contribute to global MedCM product development activities.

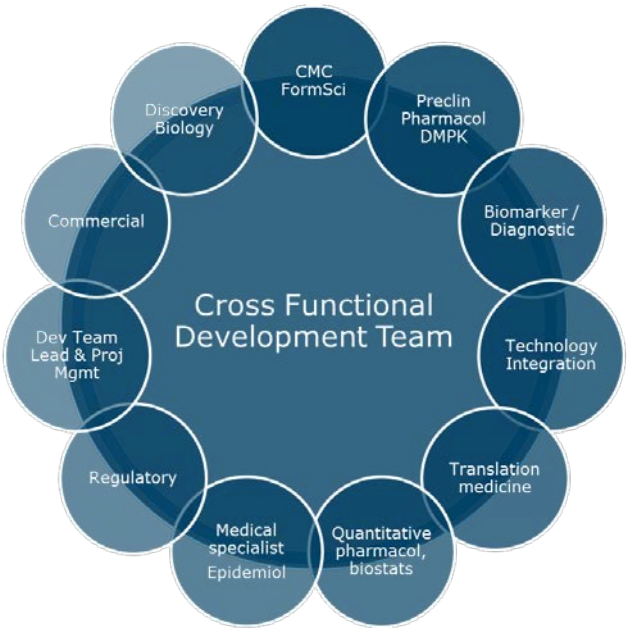

***Figure 1**: The integrated product development team. (Please note that the abbreviations above are spelled out in the Acronyms table.)*

1.3.2 People and Products

The requisite capabilities are spread across Australia and sectors (in industry followed by academia and research institutions), with the highest concentration of capability found in Victoria, then Queensland/New South Wales and South Australia. The persons who make up this community are experienced and highly professional.

1.3.3 Products and Facilities

The focus of the MedCM Consortium, discussed in section 1.2, is the advanced development of those products which are already at Technology Readiness Level[4] (TRL) 5-8 within the development cycle. The results of the recent national Report indicate that Australia has therapeutic and point of care diagnostic products, technology platforms and pharmaceutical approaches which fulfil the international TRL requirements. Furthermore, there is evidence of national regulatory, Biosafety Level (BSL) 3/4, Good Manufacturing Practice (GMP), and clinical trials capability and facilities which are needed to transition these technologies along the development pathway.

[4] Technology readiness levels (TRLs) are measures used to assess the maturity of evolving technologies during its development and in some cases during early operations.

1.3.4 Government and Preparedness

According to a 2008 report by the Commission on Weapons of Mass Destruction (WMD), a WMD attack somewhere in the world will more likely be biological rather than nuclear.[5] Whilst this has been acknowledged by the Federal Government there has been little urgency to invest in MedCM products to counter the effects of biothreats that may be used in an attack or may cause a pandemic. Irrespective of whether it is a terrorist act or natural pandemic the consequences and responses will be the same.

A review of "Strong and Secure: A Strategy for Australia's National Security"[6] and the "Counter-Terrorism White Paper: Securing Australia – Protecting our Community"[7] indicate an intention to work with the science and innovation communities to deliver effective methods of identifying, sharing and applying relevant knowledge and technologies as they emerge. Neither document recognised the importance of having a federally directed mechanism of MedCM product acquisition.

For national security policy-makers, the greatest risk may be not having sufficient types and quantities of MedCMs to meet the demands of a situation. Given such high stakes, it is imperative that policy-makers fully understand the risks inherent in commercial drug or vaccine development, and support mechanisms that make the appropriate resourcing and management of such programs[8] available to the national innovation system and advanced manufacture communities.

2. Obtaining Medical Countermeasure Products for Australia

CBR threats, emerging infectious diseases and pandemics pose imminent real and serious danger to Australia's healthcare, economy and security.[9] We have considered several alternative structures to best coordinate Australia's readiness to prepare and respond to these Bio-threats.

Each table describes, in summary, the current issues, the potential Alternative and advantages for that Alternative. The discussion provides background and the potential beneficial/detrimental aspects of that Alternative.

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[5] "*World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism Commission on the Prevention of WMD*" Proliferation and Terrorism Dec 2008 – US Congressional Report.

[6] "*Strong and Secure: A Strategy for Australia's National Security*" Department of Prime Minister and Cabinet, 23 January 2013.

[7] "*Counter-Terrorism White Paper: Securing Australia – Protecting our Community*" Department of Prime Minister and Cabinet, 2010

[8] "*The Public Health Emergency Medical Countermeasures Enterprise: Innovative Strategies to Enhance Products from Discovery Through Approval: Workshop Summary."* Washington (DC): National Academies Press (US); 2010. D, Case Studies of HHS Chemical, Biological, Radiological, and Nuclear Medical Countermeasure Development Programs, Executive Summary

[9] *Ibid at 1*

2.1 Alternative 1 - National MedCM Product Information and Procurement Service

National MedCM Product Information and Procurement Service	
Current Issues	• Differing approaches to procuring MedCMs across state, territory and Commonwealth Jurisdictions. • Lack of knowledge of entire stockpile contents and shelf-life. • Lack of knowledge about where to procure product. • Limited MedCMs because of a lack of a significant commercial market. • Limited dosages of limited MedCMs. • Inability to rotate stock.
Alternative 1	Build upon current Government capability and establish a dedicated national service which has oversight of entire national MedCM stockpile and a database of which global organisations (Government and industry) have products for immediate procurement.
Advantages	• A centralised information and management resource for health/defence businesses. • Provide practical procurement guidance. • Collate and refer disease/threat information to the appropriate national preparedness authority.

2.1.1 Discussion

A National MedCM product information and procurement service could make improvements to some of the issues associated with the current resourcing and management of the national stockpile. It would provide visibility of the available MedCMs at the state, territory and federal level; enable efficient distribution of MedCMs; and could map the severity of the disease or threat depending on the demand for a particular MedCM.

Whilst it is an important Service, it relies entirely on already developed and approved products (either in the stockpile or on the market). The majority of which are produced internationally because of the current dispersed nature of therapeutic, vaccine & diagnostic production in this country. Recently, our international partners have indicated

that there is no guarantee of the availability of MedCMs, as their needs will be met first in a time of crisis. Therefore there must be a certain level of redundancy in the MedCM product acquisition strategy so as to reduce the potential loss of life.

Australia needs to be cautious about its dependence on other nations for MedCMs as there are a number of emerging infectious diseases which are endemic and of limited interest to the major international MedCM manufacturers.

Alternative 1 does not create or sustain a national capability to develop MedCM products and therefore does not fulfil the national mandate for Government to support and grow local businesses. Alternative 1 should be considered as part of the puzzle and must work in concert with a MedCM product development capability.

2.2 Alternative 2 - Tender for each required MedCM

Tender for each required MedCM	
Current Issues	• Government doesn't tender to develop MedCMs. • Lack of tracking of each Government department requirement. • Mainly procured from overseas. • Many and varied therapeutic, vaccine & diagnostic development services offered. • Regulatory requirements for MedCM approval.
Alternative 2	Create a centralised and managed process for tendering MedCMs and evaluating outputs.
Advantages	• MedCMs developed as needed according to funds availability • Multiple respondents have the opportunity to develop MedCMs.

2.2.1 Discussion

In the last 8 years MedCM tenders let by the Government have been for the procurement of an already manufactured product for disease pathogens such as influenza, rubella, measles, *Varicella* and tetanus. The focus of the procurement program has been on pathogens which are commonly acquired within the community.

Emerging infectious disease, pandemic and CBR threats traditionally have been considered by the Australian Government in terms of surveillance and containment. There

has never been a *proactive preparedness product development program*. Changing climate and escalating cross border travel in our region has led to an expansion of disease-carrying vectors and an increase in the number of cases of pathogens traditionally acquired overseas being acquired locally. Not only do we have to deal with patients returning to Australia with unusual pathogens, they are developing them here. This becomes an increasing risk associated with future development activities in Northern Australia. In addition, there are now a number of anti-microbial resistant organisms causing morbidity and mortality within our healthcare system.

Tendering for each MedCM requires that a product has already been developed and is approved by the regulator. One advantage is that it gives multiple companies the opportunity to supply goods to the Government. The major issue with Alternative 2 is that the current tenders do not provide for long-term research and development (R&D) of newly-emerging pathogens which may affect civilian and military populations. This is a significant risk for the Government, as the time required to develop a MedCM in a pandemic situation may exceed expectation and lead to otherwise avoidable deaths.

Alternative 2 also makes the assumption that manufacturers are going to develop the MedCMs that Australia needs without clear signals from private or public sector markets. The pathogens in this region do not offer significant return on investment when considering the costs of development. Therefore, in the face of competing priorities manufacturers will develop other drugs and diagnostics with clear commercial markets and the likelihood of profitable returns.

For the tendering process to work effectively and address the need to develop national capability it should include product development. Therefore, it could act as a mechanism to enable MedCM product development as described in the other Alternatives.

2.3 Alternative 3 - Emergency Acquisition of Capability

Tender for each required MedCM	
Current Issues	• Not all infrastructure and capability in MedCM product development is known. • No Government legislation to secure use of a facility other than what might apply if war be declared. • System based on cooperation from private sector. • No Government pool of emergency funds to acquire MedCM (by procurement or development). • Regulatory/liability requirements for emergency MedCM approval and use.
Alternative 3	Create legislation which enables immediate

	Government use of infrastructure and skilled labour (PFRA, industry or academia) to develop a MedCM in a health emergency.
Advantages	• Clear strategy when health emergency arises. • Legislation and funding available when needed.

2.3.1 Discussion

Currently, there is no national emergency legislation in Australia. There is specific legislation for pandemic and quarantine issues which has the potential to be applied but has never been tested. This legislation is not applicable to the use of a MedCM production facility. Also, there is no emergency fund upon which the Government can draw for MedCM acquisition (by procurement or development). The overarching rule says 'national emergency costs come from agency, then from treasury with ministerial/cabinet approval'.

Australia uses a reactive approach in utilising industry for the manufacture of MedCMs in an emergency situation. Recently, the Government approached CSL to produce a pandemic influenza vaccine as per the existing contract to supply pandemic vaccine as part of its biosecurity role to supply to the Government and the World Health Organisation (WHO). In the future there may be circumstances where there is no existing contract and the manufacturer may not feel obliged or committed to national priorities.

To avoid a stalemate between non-Government capabilities and Government requirement national emergency legislation should contain provisions permitting the procurement and installation of additional equipment, facilities, processes or improvements to plants, factories and industrial facilities owned by private persons for MedCM development in response to a CBR or pandemic threat. The Government should also consider development of a fund to be used to appropriately compensate persons affected by acquisition of facilities and to pay for the developed MedCMs.

The domestic industrial and technological base is the foundation for national health preparedness. It is a required capability to be *sustained* for effective delivery of a MedCM in the time of a national emergency. Part of this requirement should be the need for an awareness of actual production capability, taking into account the entire production system, including shortages of resources, and develop recommended measures to strengthen capabilities for production increases during national emergencies. For this reason, an immediate response to a national emergency as provided by this Alternative only makes sense when the Government has the information about capability generated in the other Alternatives.

2.4 Alternative 4 - Independent Organisation

Independent Organisation	
Current Issues	• Dispersed and unknown MedCM product development program. • Pharmaceutical companies (large and small) have little financial incentive to develop MedCMs. • Market is small, unpredictable and limited to Government health and defence agencies. • No guarantee of product procurement at the end of the development cycle. • Regulatory requirements for MedCM development.
Alternative 4	Create an independent organisation which selects its own priority targets and programs.
Advantages	• A centralised self-sufficient company that leverages networks and technology to deliver products to market • No reliance on Government for funding or direction.

2.4.1 Discussion

There are very few companies globally, that focus entirely on MedCM product development. This is because of the significant level of risk including scientific and technical, the probability of success to licensure, the legislative/legal, financial, regulatory and organisational. In the current environment, unless there are significant attempts by the federal Government to lower these risks, it is extremely unlikely that this Alternative will have any long-term success. Some of the requisite measures to overcome perceived barriers include the Government guaranteeing a MedCM market, limiting liability, improving contracting practices, clarifying regulatory guidance and expediting regulatory processes.

National security consequences from a large-scale attack or pandemic situation should lead the pursuit of safe and effective countermeasures to protect Australia against these threats. The risks associated with MedCM development are complex and cross both the private and public domains. The only way to mitigate these risks is for all partners to work together throughout the development process.

By not being involved in MedCM product development and shifting the responsibility to an independent organisation, it is highly likely that the Government may not have the

required means to protect its citizens. Therefore, this Alternative does not fully align with Government obligation to secure Australia.

2.5 Alternative 5 - Public Private Partnership

Public Private Partnership (PPP)	
Current Issues	• No current (Government supported) MedCM product development program. • Pharmaceutical companies (large and small) have little incentive to develop MedCMs. • Reliance on overseas sources of MedCM products. • Australian Government has a role to play to address the identifiable gaps and support national MedCM product development. • Small to Medium business entities (SMEs) have contributed in-kind to task-force & waiting for full Government buy-in. • Unharnessed niche capability of Australian SMEs. • Realistic funding for MedCM products. • Regulatory requirements for MedCM development.
Alternative 5	Establish a public private partnership which is focused on the co-ordination of national capability and infrastructure to support national MedCM product development and response capability.
Advantages	The PPP may: • run as a centralised independent agency with the advice, support and guidance of Government; • follow the pharmaceutical industry best practice and standards to solve national priority CBR or infectious disease threats. The PPP may enable Government to: • access and grow product development capability and skills in SMEs for national benefit;

	• provide guidance of priority products; • reduce Australian need for external sources of MedCMs; • fulfil international obligations under the MedCM Consortium; • create a network of MedCM product development partners which includes the biotech/medtech and manufacturing industries; and • facilitate intra-governmental collaboration. • provide flexibility and ability to respond rapidly.

2.5.1 Discussion

While industry involvement in MedCM product R&D is important, it cannot be relied upon to solve all the problems (as per Alternative 4). Large pharmaceutical companies have too many disincentives and will not enter this arena sufficiently to get the job done. The small biotechs, while likely to come up with some novel development candidates, lack the experience, resources and capacity to take a development candidate through all the clinical testing and regulatory hurdles, and they lack manufacturing capacity. Therefore, by leveraging the specific expertise of each of the small biotechs, large pharmaceutical companies, academia, and government the entire countermeasures enterprise would be advanced.

A public–private partnership (PPP) is the most appropriate model to ***co-ordinate existing national capabilities and infrastructure*** to develop MedCM products aligned with national priority and support our commitment to the international MedCM Consortium (Figure 2). A PPP would support all the strategic imperatives for the establishment of an Australian MedCM Consortium which include: National Security and preparedness; leadership and commitment to our international and regional allies; capitalisation of the economic benefits of a more productive R&D sector; and the co-ordination of input from relevant federal government stakeholders.

PPPs enable the public sector to harness the expertise and efficiencies that the private sector can bring to the delivery of certain facilities and services traditionally procured and delivered by the public sector. The public sector has limited experience in therapeutic, vaccine and diagnostic development, and therefore any MedCM product development initiative must be led by industry. A PPP can harness the management and execution expertise that pharmaceutical/diagnostic industry best practice standards and systems provide. As a result it would be fully dedicated to government requirements.

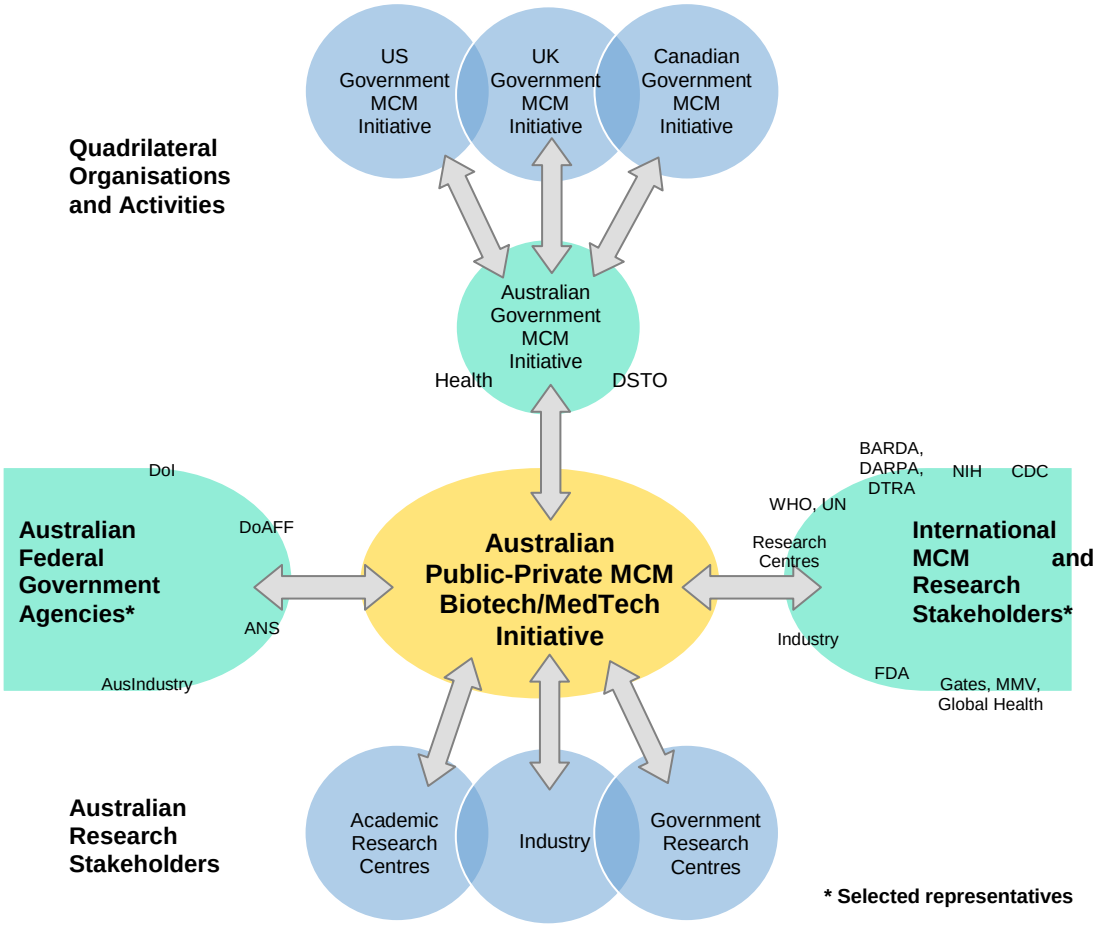

Figure 2: *Diagrammatic representation of PPP stakeholder engagement model for MedCM product development*

The ***current effort*** in a MedCM product development initiative has resulted in an industry-led Task Force who believe a PPP provides the best opportunity of the biotech/medtech community to be involved in national MedCM production. The Task-Force is seeking seed funding to conduct a product pilot initiative and ascertain the viability of a PPP in country. The PPP has been named Medical Countermeasure Products Australia (MCPA). The initial aim of MCPA would be to:

- develop a fit-for-purpose, sustainable public-private business model to support MCM product development;
- harness and focus national capability in developing MedCM products by generating measurable, validated and meaningful short-term MedCM product outcomes; and
- secure long-term funding.

Ultimately, a fully functional PPP in MedCM product development would require over $100 million enabling a therapeutic or vaccine to be prepared for purchase to the national stockpile. This type of funding would only be pursued if the pilot is successful.

The ***support required*** for any PPP must be provided by the federal government with the participation and commitment of the states. Successful MedCM product development by the PPP will require the government consider matters such as:

- develop additional R&D tax incentives for industry participating in national MedCM priority projects;
- establish guarantees to purchase MedCM products;
- encourage PPP participants to protect, own and exploit MedCM associated IP for MedCM related and unrelated commercial advantage;
- support the establishment of regulatory pathways and limit liability for MedCM products;
- encourage engagement of service organisations with relevant funding capability;
- align existing grants to encourage national and international cross-sector engagement in achieving MedCM objectives;
- prioritise and provide resource to enable the use of available government infrastructure;
- integrate the PPP into existing national emergency response networks;
- establish relationships with our regional neighbours to create a collaborative environment for discussion and research.

The ***operational structure*** of the PPP should include the following:

- Steering committee (SC) – whose primary objective is to create the business case for the PPP. This committee has responsibilities to optimise membership and business growth and diversification opportunities within established targets and ensure the long-term sustainable development of the PPP within applicable regulatory and developmental boundaries. The SC should also assess project/portfolio risk, ensuring pro-active, time-bound, dynamic, quantitative and value focused decision making. The composition of the SC includes an Executive Director, Secretary, Industry Chairman, Development Committee Chair, and Representatives from Government, Professional Services, Diagnostics and Task Force.;
- Development committee (DC) – whose primary objective is to provide technical oversight of the portfolio of activities under the purview of the PPP. The DC also manages cross-functional project teams with skilled and experienced development leadership, technical experts, project management and quality systems.
- Communications Team (CT) – whose primary objective is to (1) identify and engage stakeholders and target audiences; (2) actively seek and capture information from the these constituents and then regularly share trends with the SC and DC; 3) ensure that the message is both consistent and responsive; and 4) manage the content creation and the delivery process.

The MedCM Consortium is focused on the advanced development of technologies that are at TRL5-8. A PPP is the perfect mechanism to create opportunities and enable the innovative development of MedCMs to the benefit of all partners.

3. Conclusions

Developing and procuring MedCMs is a complex process that requires coordinated engagement across the state, territory and federal government and with countermeasure developers in private industry.[10] To date, in developing a holistic preparedness strategy for CBR threats, pandemics and emerging infectious diseases, the Australian government has focused on surveillance and containment. There has been no consideration of product development within those strategies.

Until recently, there was the misperception that in a time of crisis Australia could depend on international allies to supply the requisite MedCM. The changing global environment (increase in CBR threats, increased trade and people movement and impact of climate change on diseases distribution), has meant that our allies are more focused on having enough of their own supplies in a time of need. This creates a significant risk for the Australian government in its ability to protect its civilian and military personnel.

Australia needs to create an appropriate "MedCM product acquisition strategy". Like any good program it should not reinvent the wheel, therefore if there is already an appropriate/effective countermeasure on the market, funding should be focused on its procurement. As Australia has a number of unique emerging infectious diseases which are only of interest in the South East Asian region, these are the diseases on which our advanced R&D efforts should be focused and our global niche capability exploited.

The Alternatives which have been outlined above provide a guide as to what should be considered within any appropriately funded "MedCM product acquisition strategy". They should not be considered in isolation as they each have elements which complement the other and ultimately these Alternatives could be shaped into an effective program with global outreach.

4. Additional Information and Feedback

Any additional information or documentation can be requested from the PM-AMCMC. Feedback on this report is welcomed and can be provided to the PM-AMCMC via email (felicia.pradera@dsto.defence.gov.au).

[10] "*National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates*", GAO-14-90, Dec 27, 2013

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19. ABSTRACT

Chemical Biological and Radiological (CBR) threats, emerging infectious diseases and pandemics pose an imminent, real and serious danger to Australia's healthcare, economy and national security. In order to respond and have an all-hazard preparedness approach to these threats, Medical Countermeasures (MedCMs) are required. MedCMs can include drugs, vaccines and diagnostics (devices and materials). Currently, there exists a dependence on non-Australian sources for MedCM products however there is no assurance that these products will be available in a time of need. Alternative solutions must be considered and developed. This paper provides a strategy focused on exploring affordable and integrated capability to acquire (by development or purchase) MedCM products for Australia.