

CSL Submission to the Joint Standing Committee on Foreign Affairs, Defence & Trade

**Inquiry into the role of the private sector in
promoting economic growth and reducing
poverty in the Indo-Pacific region**

May 2014



1. Our Organisation

CSL is Australia's largest biotechnology company and a global leader in protein science and plasma-derived therapies. We are headquartered in Melbourne, Australia, with substantial operations in the United States, Germany and Switzerland. CSL employs over 12,000 people in 27 countries.

CSL has a proud history of saving lives through the development, manufacture and reliable supply of important therapies for rare and serious diseases. The organisation was established in 1916 by the Commonwealth Government to ensure an isolated Australia had its own supply of biological medicines, such as insulin, penicillin, as well as vaccines against influenza, tuberculosis and polio. In 1994 CSL listed on the Australian Securities Exchange and has grown to become a global biopharmaceutical company producing life-saving and life-enhancing products that enable millions of people around the world to lead normal healthy lives.

CSL operates two subsidiary businesses, CSL Behring and bioCSL, which are underpinned by a significant Research and Development effort.

CSL Behring is a global leader in plasma-derived therapies, with the broadest product portfolio in our industry. These therapies are used in the treatment of very serious medical conditions such as bleeding disorders, immune deficiencies, neurological conditions and in emergency critical care situations. CSL Behring operates the largest plasma collection networks in the world and manufactures plasma-derived products in the United States of America (US), Germany, Switzerland and Australia.

In Australia, CSL Behring operates a unique purpose built plasma manufacturing facility located in Broadmeadows, Melbourne. As part of Australia's policy for self-sufficiency in blood and plasma products, this facility processes plasma donations collected by the Australian Red Cross Blood Service to produce a range of life-saving therapies for Australian patients. Our Broadmeadows site plays a similar role for New Zealand, Taiwan, Singapore, Hong Kong and Malaysia and is currently undergoing expansion to enable processing of US-collected plasma for export and the production of novel recombinant proteins for clinical trials.

bioCSL is headquartered in Australia and operates one of the world's largest influenza vaccine manufacturing facilities, supplying seasonal influenza vaccines to Australia and global markets. We are Australia's first line of defence against an influenza pandemic through our ability to rapidly develop, manufacture and distribute vaccine for the Australian population in a pandemic emergency. bioCSL also produces blood typing diagnostics, is the sole manufacturer of antivenoms for the treatment of bites and stings from Australia's venomous snakes, spiders and sea creatures, and the world's only producer of Q fever vaccine for the treatment of a highly infectious disease that is carried by animals and passed to humans. Pandemic preparedness along with antivenom and Q Fever production are non-commercial activities that are provided by bioCSL to the Commonwealth Government on a partial cost-recovery basis for the benefit of the Australian community.

Research and Development (R&D) is fundamental to our commitment to saving and improving lives of people with rare and serious disease, and to our ongoing growth and commercial success as a global speciality biopharmaceutical company. R&D at CSL is headquartered in Melbourne and involves by more than 900 scientists around the world. Australia is our Centre of Excellence for early stage research and is home to many important collaborations with the country's outstanding academic research institutes. R&D activities support CSL's existing products as well as the development of new protein-based therapies. Promising new medicines in CSL's pipeline are either fully developed inhouse, or developed in collaboration or under license with other pharmaceutical companies who bring complementary resources and capabilities to the partnerships.

2. Our Philosophy

CSL believes the private sector can be an important contributor to economic growth and alleviation of poverty in developing countries. However, the challenges faced by low income countries are far too great to be addressed by individual organisations, and by monetary donations alone.

It is CSL's experience that economic and social development in low-income countries is best achieved through multi-stakeholder collaborations, where each partner contributes unique capabilities and expertise towards a shared goal.

Such collaborations should include government agencies, non-government organisations, academic institutions, philanthropic foundations and individual companies or industry coalitions. It is essential that the country beneficiary is an equal partner and decision-maker in the collaboration.

For impactful and sustainable change, collaborations must have at their foundation genuine good-will and a long-term commitment given the many challenges to be overcome. Initiatives must deliver quality of life benefits and be underpinned by robust governance and program design.

The drivers for private sector involvement in sustainable development will vary by company. For CSL, social responsibility and the benefits it can deliver to all parties is a key driver of our involvement. Because of the complex nature of our products, the opportunity for commercial returns is not a realistic proposition in the short to medium term.

Previous Relevant Reports and Submissions

CSL was one of many private organisations that shared its philosophy on private sector involvement in sustainable development in a report commissioned by the Australian Agency for International Development (AusAID) titled *Business in Development Study 2012, Australian business leaders provide insight into the delivery of business outcomes with social benefit in developing countries*.¹

Produced jointly by Business for Millennium Development and Accenture, the Report findings are very relevant to the Inquiry, and include:

- › Private enterprises can play an important role in, and indeed accelerate, the alleviation of poverty;
- › Common ground between private enterprise and prospective partners must be struck in order for effective achievement of outcomes;
- › Complexity of implementing programmes is a key barrier and obstacle, and include the following contributing factors:
 - Lack of infrastructure
 - Government capacity
 - Corruption
 - Limited education
 - Ineffective regulation;
- › Effective multi-stakeholder partnerships, involving government agencies, NGOs and other knowledgeable and highly specialised local groups, help to overcome implementation obstacles and provide a foundation for sustainable change.

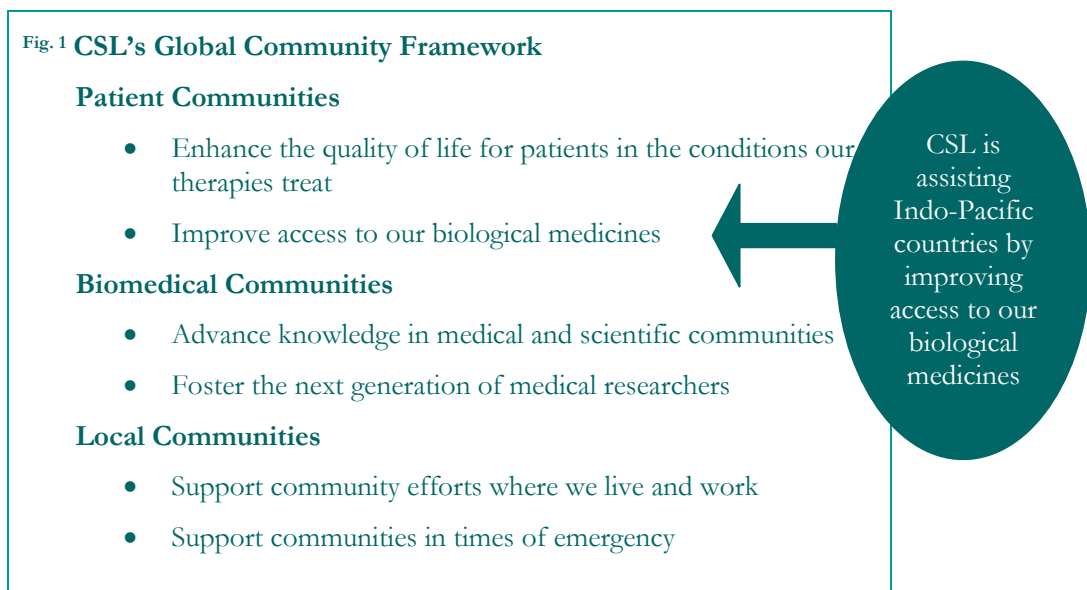
The report also found an increased role for AusAID in assisting the private sector to identify priorities in developing countries, and for AusAID to consult more widely with the business community when designing aid projects. The report further consolidates these findings and others into a framework identifying six key actions for AusAID to accelerate business engagement.

3. Our Experience

As a global speciality biopharmaceutical, CSL seeks to contribute to economic growth and poverty alleviation in developing countries through collaborations that aim to reduce the burden of disease. Specifically, we aim to contribute unique resources and expertise to improve ongoing access to the specialised medicines we make.

These efforts are guided by our Global Community Investment and Sustainable Development Framework (see Fig 1).

With our heritage and ongoing presence in Australia, CSL has contributed to sustainable development efforts in many countries in the Indo-Pacific region. Through this submission, we share with the Committee our experiences in and examples of the collaborative public health initiatives we have undertaken within the region.



3.1 Pandemic Influenza Response and Preparedness

Over the last five years CSL has actively supported international efforts to better prepare developing countries manage the threat of influenza pandemics.

In response to the *Swine Flu* threat in 2009, CSL donated 1.453 million doses of pandemic influenza vaccine to the World Health Organisation (WHO) to help at-risk, low-income countries protect against the influenza pandemic. Indo-Pacific recipient countries included Cook Islands, Nauru, Niue, North Korea, Timor, Tokelau and Tonga. Our support also included an additional gift of A\$559,322 to assist the WHO with the purchase of syringes and to support the cold-chain transport of donated vaccine to recipient countries. Furthermore, we supported the Australian Government's donation of pandemic influenza vaccine to the WHO with extensive liaison, coordination and specialist input.

Lessons learned from the Swine Flu Pandemic highlighted the structural challenges in ensuring developing countries have rapid and sufficient access to vaccine in a pandemic emergency. As such, in 2011, CSL worked with other influenza vaccine manufacturers and the WHO member countries to broker a new Pandemic Influenza Preparedness Framework². Under the Framework, all manufacturers will make additional contributions to the Global Influenza Surveillance Network, ensuring viruses with pandemic potential are rapidly detected, analysed, shared and used to produce higher quantities of vaccines at greater speed.

Additionally, CSL has committed to working towards providing at least 10% of any future pandemic vaccine output, in real time, to the WHO for use in developing countries under greatest threat.

Improving the awareness and seasonal uptake of influenza vaccine in developing countries is not only important in reducing morbidity and mortality associated with influenza, it is also an important strategy for improving pandemic preparedness. To this end, in June, 2013, and again in May, 2014, bioCSL donated 97,000 and 760,000 doses of seasonal influenza vaccine respectively in a partnership with the U.S. Centres for Disease Control and Prevention (CDC). In both instances Laos was the recipient country.

3.2 Improving Access to Haemophilia Treatment & Care

It is estimated 1 in 10,000 people suffer from haemophilia³, a rare disease affecting the ability of the blood to clot. The recommended treatment for people with haemophilia is to treat by replacement coagulation factor. In developing countries, failure to diagnose and treat haemophilia can result in death.

In an effort to improve access to haemophilia treatment and care, in 2009, CSL Behring entered into the first-ever long-term partnership with the World Federation of Hemophilia (WFH) to donate 6 million units of coagulation factor. The initial partnership also included a multi-year pledge to provide annual financial support to the WFH.

The WFH is delivering the blood clotting factor to patients in developing countries through its Global Alliance for Progress (GAP) program. GAP, a multi-partner program including other plasma product manufacturers such as Baxter and Grifols, aims to improve the diagnosis and treatment of bleeding disorders in developing countries by improving access to safe and affordable treatment and develop sustained programs for comprehensive care that countries can eventually maintain themselves.

In 2013, CSL renewed for a further three years our pledge to provide replacement coagulation factor to the WFH's GAP program. Product making up the CSL Behring donation will be manufactured at CSL's Broadmeadows plant in Melbourne, and the CSL Behring plant in Marburg, Germany. Twenty countries have participated in GAP, including China, Philippines and Thailand.

To date, GAP has established 16 national care programs and diagnosed & registered 26,381 patients with hemophilia, 2,637 with von Willebrand disease (VWD) and 1,986 with rare clotting factor deficiencies⁴.

3.3 Reducing the Burden of Cervical Cancer

Approximately 266,000 women die every year from cervical cancer. Over 85% of those deaths occur in developing countries, where women often lack access to cervical cancer screening and treatment. Virtually all cervical cancers are caused by infections of Human Papillomavirus (HPV), with just two HPV types, 16 and 18, responsible for about 70 percent of all cases.⁵

GARDASILTM, a vaccine against HPV, was initially developed through a collaboration between CSL and the University of Queensland. It was then licensed by CSL to Merck & Co. Inc. in 1995 for further development, manufacture and supply. In 2007, GARDASILTM was launched on the National Immunisation Program in Australia where more than 70% of females aged 12 to 26 have now been vaccinated.

To further expand access to this important vaccine, CSL agreed to waive royalty payments from its sale to developing countries. This effort helped Merck to lower the price of GARDASILTM in countries where the burden of cervical cancer is high and access to screening and treatment is limited.

The GAVI Alliance, a multi-stakeholder partnership involving manufacturers such as Merck & Co. Inc. and global health agencies, has been able to redress inequity of access, delivering vaccines to countries with the highest burden, such as Papua New Guinea and Laos. Since 2013, over 20 countries have been approved to introduce HPV vaccine with GAVI support, of which most are introducing HPV demonstration projects⁵.

3.4 Reducing the Burden of Snakebite

Snakebite is a serious, neglected, socio-economic problem affecting millions of lives, particularly in tropical developing countries.

Antivenoms, utilised for the treatment of envenoming, must be specific to the species responsible for the antivenoms. For this reason, and because the countries with the highest burden of snakebite are least able to afford to pay, the commercial market for antivenoms is very limited. As such, very few private providers remain in the market, leaving small, government-owned institutions and universities to produce antivenoms for their local needs. In addition, counterfeit and low quality antivenoms are becoming an increasing problem in developing countries.

The Commonwealth Serum Laboratories (as CSL was known then) developed the first Australian antivenom in 1931 (against Tiger Snake antivenom) and CSL today continues to be the only manufacturer in the world that produces Australian-specific antivenoms. bioCSL produces a broad range of antivenoms against Australia's most venomous snakes, spiders and sea creatures on a non-commercial basis for the Commonwealth Government. bioCSL has unique expertise in antivenom production and snakebite management and therefore actively contributes to regional and global efforts to address the significant burden of snakebite.

In response to a 2007 WHO report⁷ (highlighting a growing crisis in the production, accessibility and use of antivenom in regions where snakebites have their greatest public health threat), CSL worked with other manufacturers and the WHO to develop consensus guidelines for the production, control and regulation of antivenom.

We have also contributed to initiatives that seek to improve the clinical management of snakebite by helping doctors from Bangladesh, Thailand, Nepal, Papua New Guinea and Sri Lanka to travel to Australia to participate in the The University of Adelaide's world-renowned intensive training course in clinical toxinology. In 2010, CSL funded five Global Snakebite Initiative (GSI) Small Grants encouraging young researchers and clinicians in developing countries to become actively involved in snakebite prevention, treatment, rehabilitation and in conducting epidemiological and clinical research.

Closer to Australia, CSL is leading efforts to address the burden of snakebite in neighbouring Papua New Guinea (PNG). Australian and PNG share some of the same venomous creatures and therefore Australian antivenoms can be utilised for snakebite treatment in PNG, where mortality is a significant issue.

In selected regions of (PNG) Central Province deaths from snakebite have been documented to be more common than deaths from malaria or pneumonia or tuberculosis or HIV, with the Mekeo region of Central Province having one of the highest snakebite incidences in the world; the snakebite death rate in Abau sub-region (33/100,000/year) is three times higher than the reported malaria death rate in Central Province (11/100,000/year)⁸.

In 2008 we supported the Australian Venom Research Unit's efforts to provide first aid education in rural villages. Leaflet's translated in two local languages were circulated to remote areas of PNG.

In 2009 we commissioned the Nossal Institute of Global Health to review antivenom problems in PNG and recommend ways in which we can further assist.

The report identified a number of areas, and CSL in collaboration with The University of PNG, The University of Melbourne, the Port Moresby-based Charles Campbell Toxinology Centre and PNG Department of Health have been working on a new program for the secure and refrigerated supply, warehousing and distribution of antivenoms throughout PNG – ultimately seeking to provide enough of the right antivenom in the right locations to help save more lives. The proposed model also intends to conduct epidemiological research to inform future supply needs and antivenom suitability across the geographically diverse PNG. We hope to implement the new model in the 2014/15 financial year, subject to approval of antivenom provision by the Australian Government.

3.5 In Times of Emergency

We recognise that global organisations have a role to play in contributing to humanitarian programs and relief efforts. Where possible CSL is committed to supporting communities in times of emergency.

Most recently, in response to the humanitarian emergency in the Philippines caused by Typhoon Haiyan, CSL donated 1,000 ampoules of tetanus immunoglobulin to the World Health Organisation (WHO). The product, essential for the treatment of tetanus infection, was distributed by the WHO to Tacloban, the worst hit region.

In addition, employees from across our sites fundraised to support urgent relief efforts, and together with company matching, a total of US\$156,936.61 was donated to local Red Cross agencies who were best equipped to direct the contributions to the areas it was needed most.

4. Future Opportunities

In addition to these global health programs, we see four main areas of opportunity to further leverage our expertise and technical knowledge in reducing the burden of disease in the Indo-Pacific region, thereby improving social and economic outcomes. Working with other relevant partners, CSL could potentially:

- Contribute its experience and knowledge in plasma collection to improve blood safety in medical settings;
- Share its technical expertise in antivenom production to help other countries with legitimate manufacturers to enhance the quality and efficacy of their antivenoms;
- Play a regional leadership role in enhancing pandemic preparedness and response; and
- Contribute to the development of science education and biomedical research.

Achieving these goals would make significant contributions to sustainable and economic development in the region. However, they are not without significant challenges, including political instability, lack of basic infrastructure, limited education and ineffective regulation. The capacity of the health care system, medical knowledge and the supply chain network is of particular importance to the successful delivery of some of the types of programs in which we could potentially support and be a partner.

The GAVI Alliance, a private-public multi-stakeholder health initiative, has demonstrated great success in improving access to medicines and reducing disease and we think it is a business model worthy of replicating for other types of sustainable development initiatives.

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(All hyperlinks current as at 30 May 2014)