



**CSL LIMITED  
OUR CORPORATE  
RESPONSIBILITY  
2016/2017**



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## ABOUT THIS REPORT

CSL's ninth corporate responsibility (CR) report spans the financial year 1 July 2016 to 30 June 2017. Any relevant events of a significant nature that have occurred between the end of the reporting period and the publication date are also detailed. Previous CR reports are available on our website:

<http://corporateresponsibility.csl.com.au>.

Our CR report covers the businesses and operations over which we exercise direct control and incorporates CSL Limited, CSL Behring (including CSL Plasma), Seqirus, and global research and development (R&D). This includes our seven manufacturing facilities in Australia, Europe, the United Kingdom (UK) and the United States (US) as well as R&D, sales and marketing, distribution, and administration activities co-located with these facilities. Other R&D activities, sales and marketing, distribution, and administrative activities occurring away from our manufacturing facilities are also covered by this report, including the full network of donation centres, laboratories and administration offices operated by CSL Plasma.

In preparing this CR report, we have followed the Global Reporting Initiative's (GRI) Sustainability Reporting G4 Guidelines and have reported in accordance with these guidelines. A GRI content index for this report is available on our website.

CSL has sought independent external assurance of health and safety data, safety and quality data and economic contribution data contained in this CR report. Limited assurance was conducted by Ernst & Young. An assurance statement can be found on page 50. We will continue to expand assurance activities to other aspects of our CR report over the coming years.

### CHANGES TO OPERATIONS

Seqirus was established on 31 July 2015, following CSL's acquisition of the Novartis influenza vaccines business, and subsequent integration with bioCSL. Unless otherwise stated in relevant sections of this report, data for the Seqirus business has also been included.

On 13 June 2017, CSL announced an agreement to acquire an 80% equity of plasma-derived therapies manufacturer Wuhan Zhong Yuan Rui De Biological Products Co. Ltd. (Ruide) from Humanwell Healthcare Group Co. Ltd. For this CR report, data for Ruide has been excluded as the acquisition closed after 30 June, 2017.

### PROVIDE INPUT ON CSL'S CR REPORT AND PRELIMINARY SUSTAINABILITY TOPICS

CSL welcomes other input on our CR report and the preliminary results of our third sustainability materiality assessment undertaken in 2017. Take a moment to answer a few questions via our online survey, available on our website.

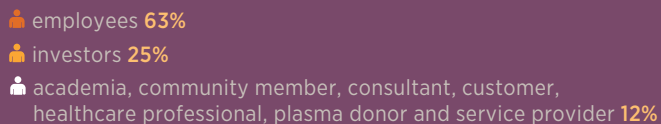
#### CONTACT

We also welcome other enquiries and feedback regarding our CR report. Communications can be addressed to:

**Patrick Castauro**  
 Director Ethics, Compliance and Sustainability  
 CSL Limited  
 45 Poplar Road  
 Parkville, VIC 3052  
[corporate.responsibility@csl.com.au](mailto:corporate.responsibility@csl.com.au)

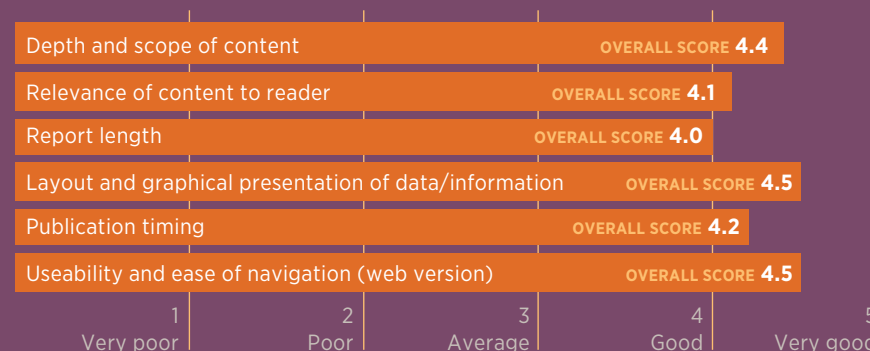
## WHAT YOU SAID ABOUT CSL'S OUR CORPORATE RESPONSIBILITY 2015/16 REPORT

### Who responded



### Report structure

Overall, respondents rated the various aspects of the CR report, such as depth and scope of content and relevance to audience, as good or higher.



### Topics

- Only seven respondents indicated other topics of interest not covered by the CR report, such as staff turnover, employee satisfaction (see page 14), departmental information and executive remuneration (see page 17). These topics and other feedback received have been incorporated in our third materiality assessment and we invite your feedback on our preliminary results.
- In 2015/16, we moved our reporting of environmental indicators to our website. There was no feedback received to indicate a need to change this approach.
- We continue to work towards providing enough of the right information to suit stakeholder needs. In line with feedback received, and in aid of improved readability, we have moved content related to how we govern and manage material topics to our website.

 This icon will be displayed throughout the report to indicate more information is available on CSL's website: <http://corporateresponsibility.csl.com.au>.

## MESSAGE FROM THE CHIEF EXECUTIVE OFFICER AND MANAGING DIRECTOR

Dear stakeholders

I am pleased to present to you CSL's ninth corporate responsibility report.

Reflecting on our performance for the year ending 30 June 2017, there are a number of achievements and challenges to report.

CSL delivered an exceptional performance, distributing close to US\$7 billion in employee wages and benefits, supplier payments, shareholder returns, government taxes and community contributions, an increase of 13% on the prior period. This excellent result reflects our commitment to strong corporate governance and the successful execution of our strategy.

For a biotechnology company that develops and manufactures life-saving and life-enhancing therapies, a focus on product safety and quality is fundamental. This year our manufacturing facilities were subject to 343 regulatory audits resulting in no changes to our product marketing licences; however, our systems and processes did detect the need for four voluntary safety related recalls. This is a small number given the total volume of

product distributed, but product safety and quality remains an area of focus and continues as our top sustainability priority.

This year we saw increases in some of our employee health and safety metrics, such as lost time and days lost. Our sites have refocused efforts on personal accountability for safety with programs targeted at personal awareness, potential hazard assessment before work, behaviour observation and feedback, and increasing involvement in safety activities.

Over the reporting period, we demonstrated in numerous ways how sustainable growth can be achieved through innovation. As part of our broad and differentiated product portfolio we have launched in a number of countries our novel recombinant coagulation factors for the treatment of haemophilia A – AFSTYLA® and haemophilia B – IDELVION®, registered in the United States the first and only self-administered subcutaneous prophylactic therapy to prevent hereditary angioedema (HAE) attacks – HAEGARDA®, and commenced the development of new breakthrough medicines by entering first-in-human studies for three new monoclonal antibodies.

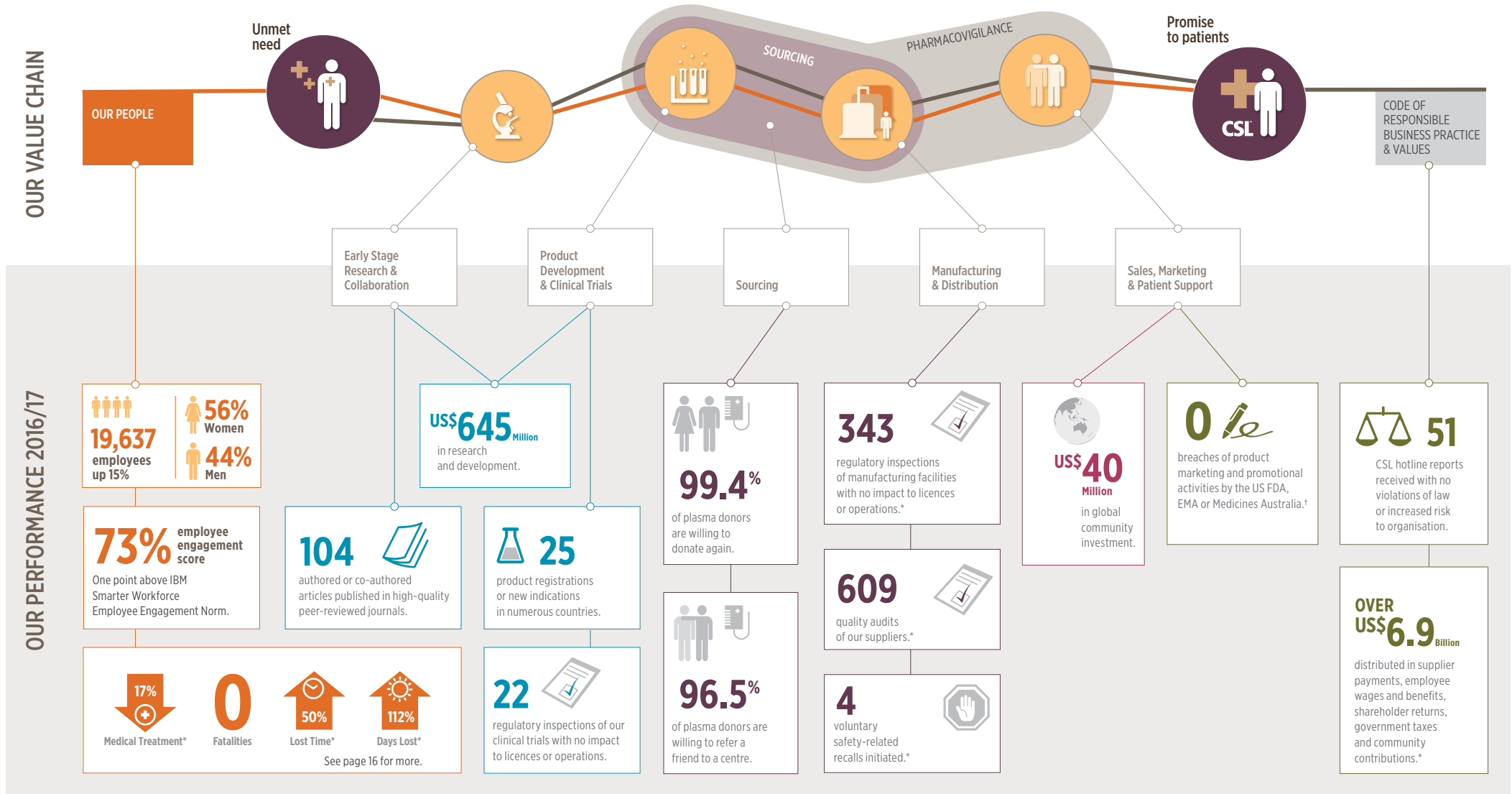
Our people are critical to our performance, and we've seen our workforce also grow by 15% compared with the previous year. Creating a culture where our employees are motivated and driven to deliver on our promise to patients is vital. This year we refreshed our organisational values with a greater emphasis on focusing on patients. Alongside our remaining values of innovation, superior performance, integrity and collaboration, an unwavering focus on placing patients at the core of all we do will drive the right decision-making and stakeholder outcomes. Our recent employee feedback results see our workforce as engaged, which my team seeks to preserve and grow.

Please take some time to share with us your thoughts on our report via our anonymous survey, available on our website: <http://corporateresponsibility.csl.com>.

**Paul Perreault**  
Chief Executive Officer  
and Managing Director



## CORPORATE RESPONSIBILITY PERFORMANCE SUMMARY



\* 2016/17 data externally assured

† EMA = European Medicines Agency, FDA = Food and Drug Administration

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# 01

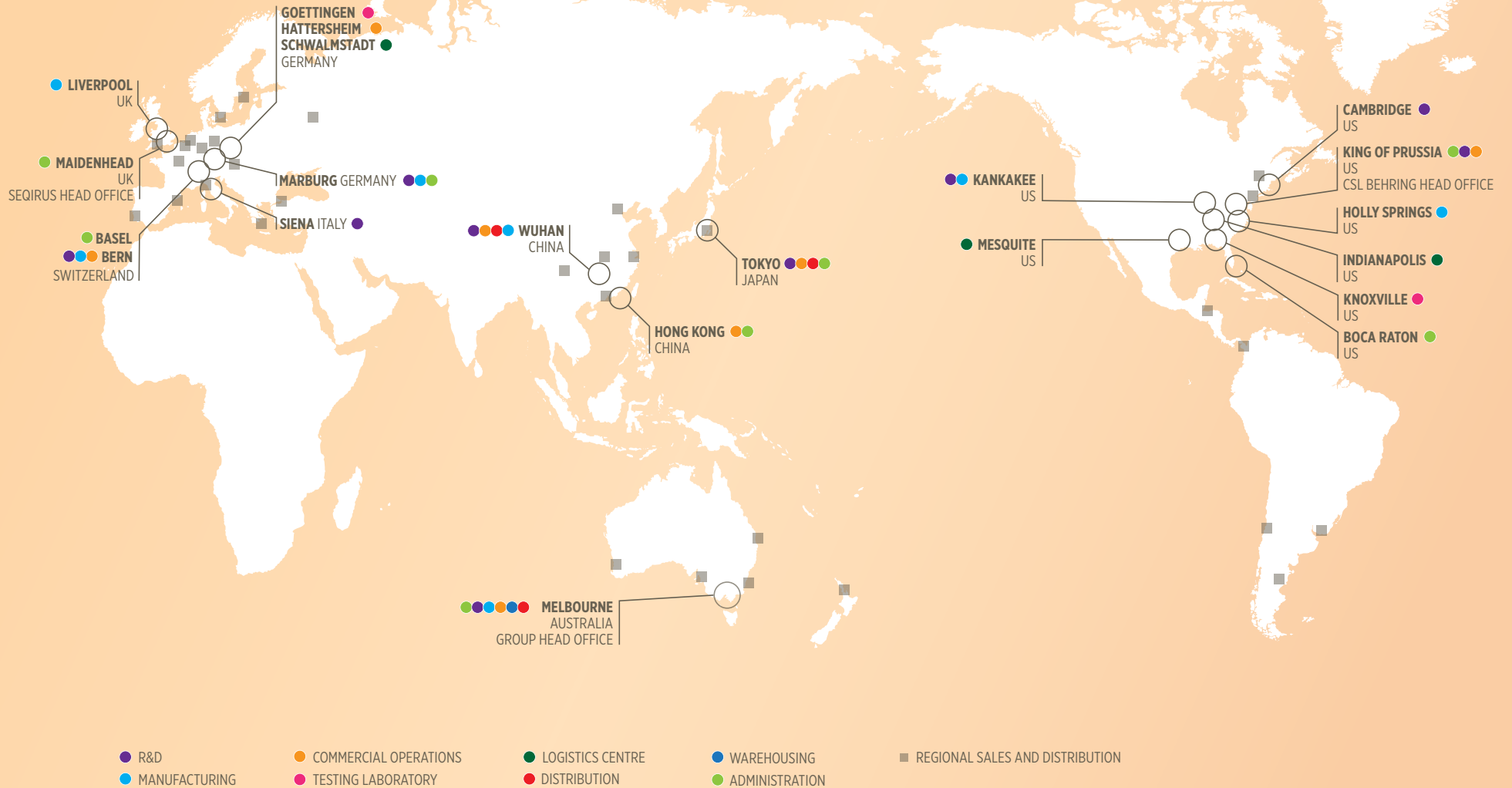
## OUR ORGANISATION

With nearly 20,000 employees operating in over 30 countries, CSL generated revenues in 2016/17 totalling US\$6.9 billion.

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## 01 OUR ORGANISATION





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## 01 OUR ORGANISATION CONTINUED

### 1.1 OUR BUSINESSES

#### CSL BEHRING

CSL Behring is a global leader in biotherapies with the broadest range of quality products in our industry and substantial markets in North America, Europe, Asia and Australia. Our therapies are indicated for treatment of bleeding disorders including haemophilia and von Willebrand disease, primary and secondary immunodeficiencies, hereditary angioedema, neurological disorders and inherited respiratory disease. Our products are also used to prevent haemolytic disease in newborns, for urgent warfarin reversal in patients with acute major bleeding, to prevent infection in solid organ transplant recipients and treat specific infections, and to help victims of trauma, shock and burns.

From our emerging family of recombinant coagulation products that aim to dramatically improve the lives of patients with bleeding disorders, to industry-leading immunoglobulin and specialty products that are shifting treatment paradigms around the world, CSL Behring knows how to meet the needs of these unique populations.

With an integrated manufacturing platform with production facilities located in the United States (US), Germany, Switzerland and Australia, we use the most sophisticated production methods available and meet or

exceed stringent international safety and quality standards. CSL Plasma, a division of CSL Behring, operates one of the world's largest and most efficient plasma collection networks, with more than 170 centres in the US and Europe.

Each step of our manufacturing process – from plasma donor to patient – reflects CSL Behring's unyielding commitment to ensuring our products are safe and effective.

#### SEQIRUS

Seqirus was established on 31 July 2015, following CSL's acquisition of the Novartis influenza vaccines business, and subsequent integration with bioCSL. Seqirus is the world's second largest influenza vaccine company and a major partner in the prevention and control of influenza globally. It is a reliable supplier of influenza vaccine for Northern and Southern Hemisphere markets and a transcontinental partner in pandemic preparedness and response.

Seqirus operates state-of-the-art production facilities in the US, the United Kingdom (UK) and Australia, utilises both egg-based and cell-based manufacturing technologies and offers novel products, including an adjuvanted seasonal influenza vaccine. It has leading research and development (R&D) capabilities, a broad and differentiated product portfolio and commercial operations in more than 20 countries.

In Australia and the Asia Pacific region, Seqirus is a leading provider of in-licensed vaccines and specialty pharmaceuticals. It also manufactures and markets diagnostics for immunohaematology laboratories and is the sole supplier of a unique range of products made in the national interest for the Australian Government, including antivenoms and Q fever vaccine.

#### RESEARCH AND DEVELOPMENT

CSL continues to grow investment in the development of protein-based medicines to treat serious human illnesses. Today, most of our licensed medicines are purified from human plasma. With the launch of our best-in-class recombinant coagulation factors, CSL has also built and is using the capabilities required to develop new and innovative products using recombinant technology. Global R&D activities support CSL's existing licensed products and development of new therapies that align with our technical and commercial capabilities in immunoglobulins, specialty products, haemophilia and coagulation therapies and breakthrough medicines.



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### 1.2 OUR PROMISE

CSL's ultimate strategy is to deliver value through fulfilling unmet needs and enhancing patient experience. With patients at the core of our focus, we also strive to deliver sustainable financial growth for our investors. We achieve this through high-quality, focused innovation capabilities, operational excellence and global commercial strength. Across our value chain, employees drive our strategy and underpin the delivery of our promise, while our Code of Responsible Business Practice sets the foundation for making good decisions across the organisation.

OUR VALUES BIND THE CSL GROUP OF COMPANIES TOGETHER THROUGH A SHARED COMMITMENT TO:

**PATIENT FOCUS** WE DELIVER ON OUR PROMISE TO PATIENTS

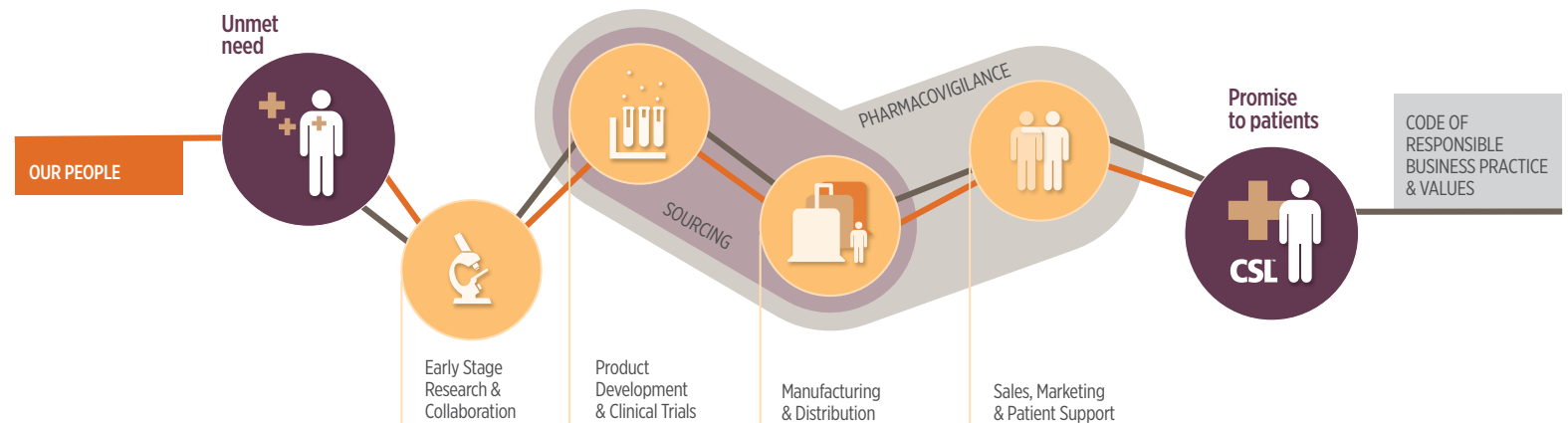
**INNOVATION** WE TURN INNOVATIVE THINKING INTO SOLUTIONS

**INTEGRITY** WE WALK THE TALK

**COLLABORATION** WE ARE STRONGER TOGETHER

**SUPERIOR PERFORMANCE** WE TAKE PRIDE IN OUR RESULTS

### CSL'S VALUE CHAIN



## 01 OUR ORGANISATION CONTINUED



### 1.3 OUR APPROACH TO CORPORATE RESPONSIBILITY

Corporate responsibility (CR) is governed by a global steering committee reporting to the Chief Executive Officer and Managing Director (CEO). The CR Committee is led by CSL's Executive Vice President, Quality and Business Services. Supporting the Chair are senior executive members from finance, legal and risk management, research and development, human resources, manufacturing, commercial operations, communications and corporate affairs.

Over the reporting period, the CR Committee supported the execution of CSL's third global sustainability materiality assessment (results will be published in 2018). In addition, the CR Committee drives the awareness, integration and continuous improvement of CR throughout the company, ensuring alignment with CSL's strategic goals and operational priorities.

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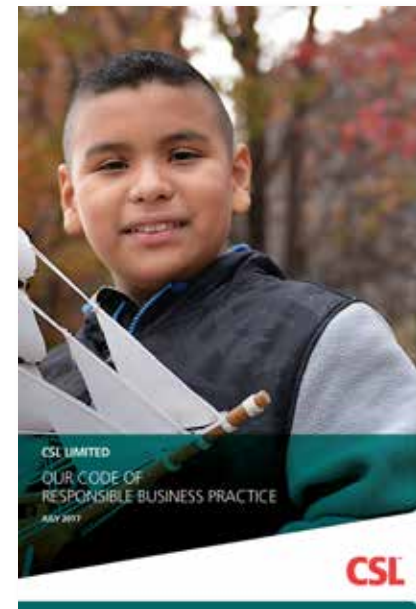
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### OUR COMMITMENT TO ETHICAL BEHAVIOUR

On 1 July 2017, CSL released to all employees a third edition of the Code of Responsible Business Practice (our Code). Our Code critically sets out the rights and obligations of our employees and affirms our commitment to our stakeholders for the highest standard of conduct in all that we do. The third edition of our Code provides greater guidance on how to manage conflicts of interest; covers topics such as trade compliance, intellectual property and tax; gives clarity on our approach for both the giving and receiving of gifts; and affirms our commitment on the prevention of counterfeit medicines and modern slavery.

Stakeholders are able to anonymously bring instances of alleged inappropriate conduct to our attention via CSL's global hotline. From 1 July 2016 to 30 June 2017, 51 such instances were raised for the attention of management. For substantiated allegations, corrective actions were taken to the extent warranted. No allegations resulted in any regulatory action or action by law enforcement authorities and there was no indication of any increased risk profile.



### STAKEHOLDER ENGAGEMENT

At CSL, we regard stakeholder engagement as a foundation of corporate responsibility. Our key stakeholders are those who are potentially affected by our operations or who are interested in how we address our strategic priorities. Engaging with each identified stakeholder group is therefore very important to ensure we understand their expectations and respond to their various interests and concerns. We strive to establish appropriate channels to engage with each of our stakeholders and ensure they can voice their perspectives and concerns throughout our value chain.

CSL's commitment is not only to develop active listening with regard to the changing expectations of our diverse stakeholders, but also to ensure transparent disclosure on how we are addressing those expectations. Every year, we notify our stakeholders of the publication of our CR report, and provide them with access to an anonymous survey where they can provide feedback on the different aspects of our reporting (for more on stakeholder responses to our 2015/16 report see page 3).



## 01 OUR ORGANISATION CONTINUED

### 1.4 MATERIAL ASPECTS

Identifying and managing sustainability aspects that are material to CSL is very important to us, given their potential to positively and negatively impact our business, our people and the communities we operate in. We use our internal Risk Management Framework in applying a consistent approach in assessing these risks from both a business and key stakeholder perspective.

CSL's Global CR Committee has overall responsibility for the materiality process and executes on a biennial basis a global sustainability materiality assessment. In 2015/16, we concluded our second such assessment and followed the Global Reporting Initiative (GRI) standards of sustainability context, materiality, completeness and stakeholder inclusiveness through our process of identification, review and prioritisation. As CSL completed the materiality process prior to the acquisition of the Novartis influenza vaccine (NIV-IS) business, aspects related to this entity were not included in our materiality process.

We have mapped our top 15 material sustainability aspects to the relevant boundaries along our value chain (see the table, shown right).

Aspect (in order of importance)	Key stakeholders impacted	Value chain boundary	Relevant section in this report
<b>PRODUCT SAFETY AND QUALITY</b>	Patients and patient groups; customers; regulatory agencies; employees; healthcare professionals	Product development to sales and marketing	Product safety and quality (page 28)
<b>CONDUCT OF CLINICAL TRIALS</b>	Patients and patient groups; regulatory agencies; healthcare professionals	Product development and clinical trials	Innovation (page 20)
<b>ETHICAL MARKETING</b>	Patients and patient groups; regulatory agencies; healthcare professionals; industry associations	Sales and marketing	Marketplace (page 39)
<b>PLASMA DONATIONS AND DONORS</b>	Regulatory agencies; plasma donors	Sourcing	Product safety and quality (page 30)
<b>BRIBERY AND CORRUPTION</b>	Investors/shareholders/debt providers; customers; regulatory agencies	Across the value chain	Marketplace (page 37)
<b>INNOVATION PROCESS</b>	Research partners; patients and patient groups; healthcare professionals	Early stage research and collaboration to product development and clinical trials	Innovation (page 21)
<b>INNOVATION MANAGEMENT</b>	Research partners; investors/shareholders/debt providers	Early stage research and collaboration to product development and clinical trials	Innovation (page 20)

## 01 OUR ORGANISATION CONTINUED

Aspect	Key stakeholders impacted	Value chain boundary	Relevant section in this report
ANTI-COMPETITIVE BEHAVIOUR	Investors/shareholders/debt providers; customers; regulatory agencies	Sourcing to sales and marketing	Marketplace (page 34)
SOLE SUPPLIER OF CRITICAL MEDICAL PRODUCTS	Patients and patient groups; customers; healthcare professionals	Sourcing to sales and marketing	Product safety and quality (page 31)
HUMAN RIGHTS	Employees; business partners; local communities and NGOs	Sourcing and across human capital	Our organisation (page 17) Product safety and quality (page 31)
DATA PROTECTION AND PRIVACY	Patients and patient groups; customers; regulatory agencies; employees; healthcare professionals; plasma donors; research partners; business partners	Across the value chain	Marketplace (page 39)
ACCESS TO HEALTHCARE – FAIR PRICING AND AFFORDABILITY	Patients and patient groups; customers; employees; local communities and NGOs	Sales and marketing	Marketplace (page 37)
TRANSPARENCY OF INTERACTIONS WITH GOVERNMENT	Customers; regulatory agencies	Across the value chain	Marketplace (page 34)
TARGETED COMMUNITY SUPPORT, INCLUDING FULL CYCLE OF PATIENT CARE	Patients and patient groups; local communities and NGOs	Across the value chain	Community (page 41)
COUNTERFEIT MEDICINES	Patients and patient groups; customers; regulatory agencies; healthcare professionals	Sourcing to sales and marketing	Product safety and quality (page 31)

Full list of topics, including the relevant GRI G4 aspect, can be found on our website.

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### 1.5 OUR PEOPLE

Managing our people responsibly and respectfully, while inspiring them to achieve superior performance, is critical to the ongoing success of our business. We promote collaboration, innovation, diversity, safety, health and wellbeing in the workplace. We strive to equip our people with the right skills to perform their roles by providing them with development opportunities to learn new skills, fulfil their career aspirations and achieve a promising future with CSL. Finally, we reward and recognise our people for their contributions to our business success. Executive management teams, each including a senior human resources (HR) professional, are accountable for implementing HR practices that fulfil our employment responsibilities, provide a supportive and inclusive environment and support our business strategy.



### OUR WORKFORCE

CSL's global workforce has grown to a total of 19,637 employees (as at 30 June 2017) – up 15% from the previous year. Our people are employed in more than 30 countries across a number of geographic regions. As with past years, our workforce continues to grow to accommodate an expanding network of CSL Plasma centres, an expansive market presence of more than 60 countries and a growing footprint across our manufacturing sites in Australia, Germany, Switzerland, the UK and the US.

### CULTURE AT CSL

We value our employees' opinions at CSL. Our newly designed employee feedback survey was administered in April/May 2017. The feedback survey will be conducted biannually with results shared openly and transparently with employees. Leadership teams will examine the results and develop action plans for areas of improvement while recognising areas of strength. Our first set of results provided insight into what engages and motivates our people and how we are performing regarding our strategy to "Create a culture that attracts, develops and retains best talent." The results of the survey found that CSL's score of 73% employee engagement favourability is one point above the global norm (IBM Smarter Workforce Employee Engagement Index). The solid engagement scores are underpinned by strong, positive responses to the questions regarding pride in working for CSL and the belief that we have a motivating vision and strategy for the future.

The important work that CSL does, which is focused on patients and the health of the communities we serve, is also a significant attraction and retention factor for talent.

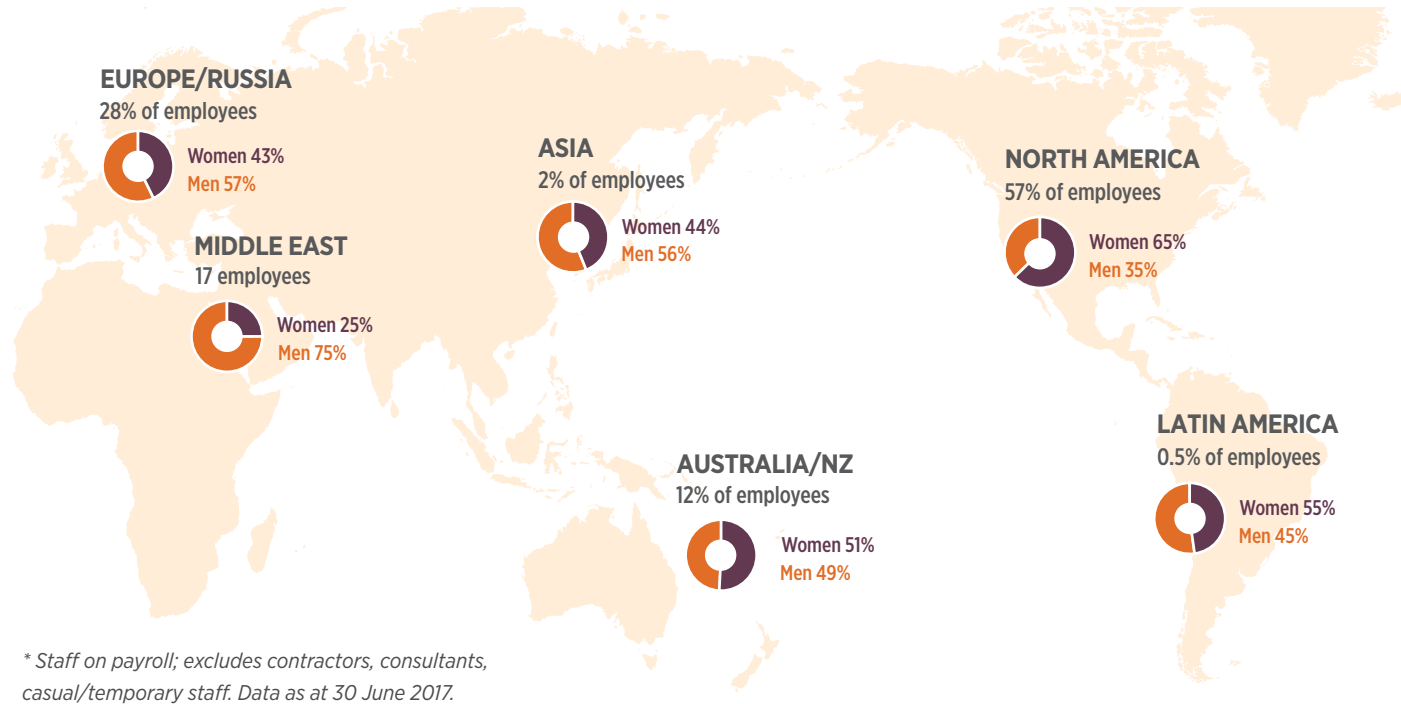
People are inspired by working in a values-based environment such as CSL, where they have the opportunity to perform meaningful work and serve the greater good. It is this sense of purpose that shapes the globally collaborative and collegial culture of CSL. We partner across boundaries to bring the best, most innovative solutions forward for our patients.

In 2016/17, our talented people and innovative workplace were recognised. Recognitions of note include the prestigious 2017 Industry Innovator Award from the National Organization for Rare Disorders (NORD) and ranking on IgeaHub's list of Top 15 Biotech Companies in the world for 2016. We also received recognition for our culture of diversity and inclusion. Kankakee, in the US, was acknowledged by the US Department of Defense for going "above and beyond" in employing members of the military. CSL Behring Marburg, Germany, received an award from the Economy Minister of the German State for "GreenZone", an employee wellbeing concept.

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### DIVERSITY

CSL promotes an inclusive culture that contributes to our growth and performance by harnessing the capabilities and experiences of a diverse workforce. Our focus on diversity and inclusion respects our people and benefits the business and stakeholders we serve around the world.

We view diversity through a broad array of differences in people, including across attributes of gender, nationality, ethnicity,

disability, sexual orientation, generation/age, socioeconomic status, professional and educational background, and global and cultural experience.

CSL has a global diversity policy and is building a global diversity platform, which is integral to our enterprise-wide talent and culture strategies. We support an inclusive work environment where our people have equitable access to career opportunities, training and benefits.

In 2016/17\*, females comprise the majority of employees at 56%, a modest shift upwards from the prior year, with males at 44%. We have once again achieved our target percentages for female representation in leadership, which is 30% for senior executive positions and 40% for other people management positions. Of our senior director and above hires, 33% were female, which aligns with global benchmarks in our major geographies.



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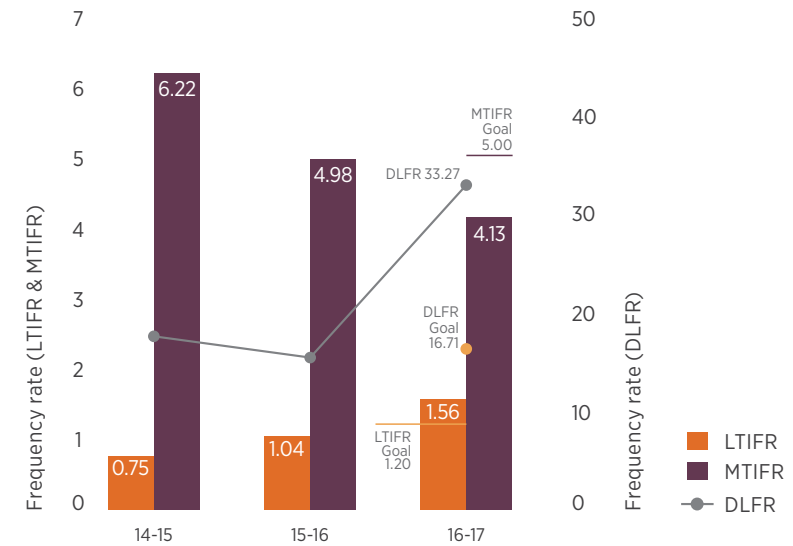
### EMPLOYEE HEALTH AND SAFETY

CSL has an Environment, Health, Safety and Sustainability (EHS<sup>2</sup>) Strategic Plan, which ensures its facilities operate to industry and regulatory standards. This strategy includes compliance with government regulations and commitments to continuously improve the health and safety of the workforce as well as minimising the impact of operations on the environment. To drive this strategy, a Global CSL EHS<sup>2</sup> Management System Standard is under development with particular regard to the international standards, ISO 14001 Environmental Management Systems and draft ISO 45001 Occupational Health and Safety Management Systems.

Employee safety targets are set annually through a collaborative process with business leaders and are intended to motivate CSL to make progress towards an injury and illness-free workplace. Against the prior comparable period and emanating from very low bases, there were increases across two indicators: the lost time injury frequency rate increased by 50%, with no discernible clusters of causation or indications of a trend in type or location of incidents; and the days lost frequency rate more than doubled due to several extended injury recovery times. The sites continue with return-to-work programs designed to provide restricted work activity to minimise lost time and aid in rehabilitation and recovery. In addition, we have refocused efforts on personal accountability for safety with programs targeted at personal awareness, potential hazard assessment before work, behaviour observation and feedback, and increasing involvement in safety activities.

CSL's medical treatment incident frequency rate decreased by 17% and we continued our long-standing record of no employee or contractor fatalities and zero safety violations or fines.

### OUR HEALTH AND SAFETY PERFORMANCE\*



\* The frequency rate is the number of occurrences of injury or disease for each one million hours worked. LTIFR = lost time injury frequency rate (occurrences that resulted in a fatality or time lost from work of one day/shift or more). DLFR = days lost frequency rate. MTIFR = medical treatment incident frequency rate (occurrences which were not lost-time injuries and for which medical treatment was administered). Contractor injuries and hours are not included; however, injuries and hours for directly supervised workers, such as contingent workers, have been included for some sites. Employee hours have been estimated by each site and the estimation method varies based on region.



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### PERFORMANCE AND TALENT MANAGEMENT

Our performance and talent management processes ensure we:

- Have leaders who advocate and are role models for critical behaviours in alignment with our newly refreshed CSL values (Patient Focus, Innovation, Integrity, Collaboration, Superior Performance);
- Set clear expectations for all employees in support of our strategic objectives and strategy execution;
- Develop a pipeline of future managers and leaders to drive continued growth;
- Provide performance coaching and feedback to help people succeed;
- Attract, retain and develop talented individuals who possess critical capabilities and contribute to our business success;
- Hire a qualified, diverse pool of people across the globe; and
- Invest in reward and recognition programs that fulfil our commitment to our people.

We provide management with strategies and training to ensure that feedback and developmental coaching occurs throughout the year and is not limited to finite sessions. Development planning is an important aspect of performance management and is

encouraged for all professional staff, involving structured discussions to identify development needs and actions, and opportunities to learn. The complete implementation of a leading-practice human resources system enables us to readily capture and more effectively manage the performance and development plans of our people.

CSL also invests in the development of its managers through global and local programs. These programs include Management Essentials, Leadership Evolution Program, Situational Leadership, Early Career Development Programs (through internships and apprenticeships), Future Leaders/ Graduate Program, executive leadership summits, mentoring for multiple levels of leadership and next generation talent, online learning programs for managers of CSL Plasma and several local programs focused on site-specific leadership development needs.



### EXECUTIVE REMUNERATION

At the 2017 Annual General Meeting (AGM), CSL received a 'for' vote for our 2017 Remuneration Report. This comes after receiving an 'against' vote of 26% (also known as a 'first strike') on the resolution to adopt the 2016 Remuneration Report.

Since the 2016 AGM, members of the Board met with a number of shareholders to better understand their concerns. The key messages were to focus on simplicity and transparency, reward real achievement, ensure executive alignment with shareholders' interests, and do a better job of explaining our approach to rewarding senior executives.

Following this, we have made many changes to how we now approach remuneration, coupled with the importance of developing a single, globally competitive pay design for senior executives that secures our future as a global biopharmaceutical company. We have implemented the new CSL executive pay design which we believe will strengthen CSL and gain even better alignment between shareholders and executives.

The CSL Board's continued remuneration governance focus is significant and actively engaged on making sure that CSL has a system that both shareholders and executives will agree is helping to drive sustainable growth in our business over the longer term.

### HUMAN RIGHTS

At CSL, we are committed to treating our people in a lawful and fair manner, and seek to engender a workplace culture of mutual trust and respect. Our Code of Responsible Business Practice sets our approach and is supplemented by a number of global and local policies that entail obligations and practices for workplace standards across the many regions in which we operate. In 2016/17, our Code was updated to reinforce CSL's position on modern slavery:

*We forbid the solicitation, facilitation, or any other use of slavery or human trafficking. Under no circumstance should any engagement with CSL deprive individuals of their freedom.*

CSL believes the aspect of human rights is more relevant to our supply chain, and efforts to better ensure alignment with our Code continue.

To further enhance our expectations of employee conduct in the workplace, over the reporting period, 90% of CSL employees undertook Mutual Respect training delivered by our global learning management system partner.

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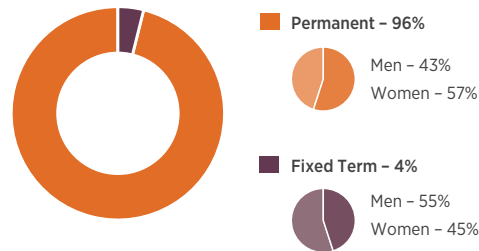
## 01 OUR ORGANISATION CONTINUED

### OUR PEOPLE

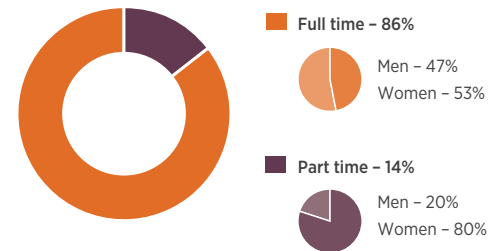
#### OUR TOTAL WORKFORCE NUMBERS\*

Division	16-17
CSL Behring	8,543
CSL Plasma	8,409
CSL Limited†	486
Seqirus	2,199
<b>TOTAL</b>	<b>19,637</b>

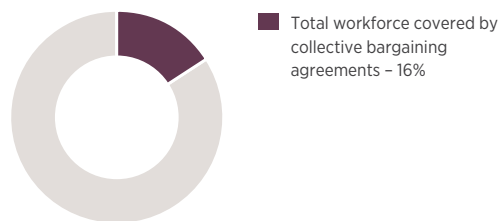
#### OUR TOTAL WORKFORCE BY EMPLOYMENT CONTRACT\*



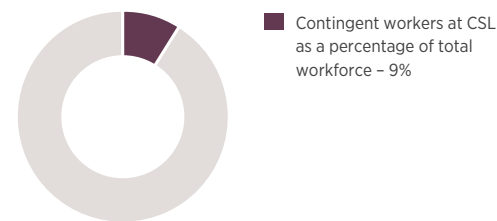
#### OUR PERMANENT WORKFORCE BY EMPLOYMENT CONTRACT\*



#### OUR TOTAL WORKFORCE COVERED BY COLLECTIVE BARGAINING AGREEMENTS\*



#### CONTINGENT WORKERS (CONTRACTORS) AGAINST TOTAL WORKFORCE\*



\* Staff on payroll and excludes contingent workers, contractors, consultants, casual/temporary staff. Data as at 30 June 2017. In 2017, CSL concluded the rollout of the Global Human Resource Information System for all employees and contractors. Historical data is not available. CSL employees supervised 1,812 contingent workers (contractors), representing 9% of our total workforce.

† CSL Limited includes CSL Corporate and Australian-based R&D staff.

# 02

## INNOVATION

A dedicated focus on product research and development (R&D) and execution excellence ensures we are well positioned to deliver new and improved therapies for unmet patient needs. For CSL, R&D is a critical driver of sustainability.

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## 01 INNOVATION CONTINUED

### GOVERNANCE

The CSL R&D governance framework is a system of committees and employees with clearly allocated decision-making rights and defined responsibilities, designed to ensure that R&D effectively supports the delivery of CSL's strategic objectives. The framework is designed to allow high quality, timely decision-making for individual projects and the global R&D portfolio.



### 2.1 PERFORMANCE

In 2016/17, CSL invested US\$645 million in R&D efforts across our businesses. During the reporting year, we achieved 25 product registrations or new indications for serious diseases.

A major highlight was the United States (US) registration of HAEGARDA®, the first and only self-administered subcutaneous prophylactic therapy to prevent hereditary angioedema (HAE) attacks. Further achievements include registration in Japan of IDELVION®, our long-acting fusion protein linking recombinant coagulation factor IX with recombinant albumin, for the treatment of haemophilia B, and registration in Europe of AFSTYLA®, our novel factor VIII single chain, indicated for adolescents and adults with haemophilia A.

Seqirus also registered quadrivalent influenza vaccine in Australia and the US for use in people aged 18 years and above.

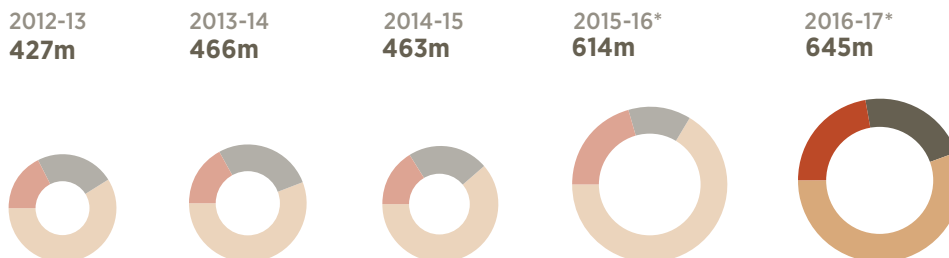
Significant progress has been made in the development of new breakthrough medicines over the past year. Two new monoclonal antibodies (MAbs) progressed to first-in-human studies: CSL324, designed to treat inflammatory diseases, and CSL312, for treatment of HAE. In addition, a third MAb, CSL346, designed to control glucose absorption in type 2 diabetics, will enter the clinic shortly. All three MAbs have novel mechanisms of action and the potential to treat multiple indications in patients.

Results from our Phase IIb clinical trial designed to evaluate the safety and proof of mechanism of CSL112, a novel apolipoprotein A-I infusion therapy, were presented in November 2016. CSL112's unique mechanism of action, the removal of cholesterol from atherosclerotic plaque in the arteries, was confirmed by the study.

Over the reporting period, 22 inspections of our clinical trials were undertaken by regulatory agencies with no impact on clinical trial licences or operations.

Collaboration with external partners continues to provide CSL with important new opportunities to develop novel therapies for patients. In January 2017, we announced an exciting new research collaboration and worldwide licence agreement with Momenta Pharmaceuticals, Inc. to develop and commercialise their recombinant Fc multimer proteins for use in controlling inflammation associated with autoimmune diseases. Clinical trials are expected to start in late 2017 to early 2018.

### RESEARCH AND DEVELOPMENT INVESTMENT (US\$ MILLIONS)



- **New Product Development** activities focus on innovative new therapies for life-threatening diseases.
- **Market Development** strategies seek to bring therapies to new markets and new indications.
- **Life Cycle Management** ensures continuous improvement of existing products.

\* Includes R&D for CSL Behring and Seqirus.

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### 2.2 COLLABORATION

Collaboration is at the heart of CSL's success. Strong and productive partnerships are essential for innovative scientific discoveries and for developing those ideas into new medicines for patients. Collaboration exists throughout all parts of our business, with patients, patient groups and clinicians as well as research associations, and with medical research institutions, universities and hospitals.

The majority of CSL's early stage research scientists are located at the University of Melbourne's internationally recognised Bio21 Molecular Science and Biotechnology Institute in Parkville, Australia. We have been a partner with Bio21 and their group of approximately 500 research scientists since 2007. Our research scientists find Bio21 an attractive and intellectually stimulating place to work, and the cross-cultivation of ideas from academia to industry helps translate science into life-saving medicines.

In 2016, Australian Prime Minister Malcolm Turnbull announced a substantial A\$36.4 million, 5000m<sup>2</sup> expansion of the Bio21 Institute to be completed in early 2018. The new state-of-the-art facility will house CSL's Global Research and Translational Medicine Hub, where we expect to double the presence of CSL research scientists from 75 to around 150. Our increased presence at Bio21 will enable us to increase our collaboration with University of Melbourne researchers and other research institutes and hospitals in the Parkville precinct. It will also provide an expanded base for new national and international partnerships and provide a powerful way to build our long-term pipeline of medical therapies.

We are also involved in several initiatives to aid and accelerate the commercialisation of promising biomedical research. In 2016, CSL established a new partnership with QIMR Berghofer Medical Research Institute, in Brisbane, Australia, to support the translation of the institute's scientific discoveries into innovative new medical technologies.

Through a commitment of almost A\$25 million, CSL is also participating in the newly established Brandon Capital-led A\$230-million Biomedical Translation Fund and the existing A\$200-million Medical Research Commercialisation Fund (MRCF). These funds, the largest life science funds in Australia's history, will invest in the development of promising Australian biomedical discoveries and increase the pool of products suitable for later stage development.

Furthermore, we are committed to supporting the next generation of medical researchers through partnerships, financial assistance, mentoring and training. In July 2016, we became an inaugural partner of a new training centre for biopharmaceutical innovation established at the University of Queensland. The centre's training program is designed to prepare industry-ready scientists by providing work experience and an improved

understanding of R&D in a commercial environment. We hope the centre will result in a pool of industry-ready scientists who will directly contribute to novel life-saving, life-changing medicines for patients across the globe.

Over the reporting period, our scientists and collaborators have continued to publish high-quality scientific research authoring or co-authoring 104 articles in peer-reviewed journals.



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## 01 INNOVATION CONTINUED

### 2.3 CLINICAL TRIALS

CSL continues to invest in clinical development activities as part of our R&D strategy. In 2016/17, CSL commenced eight new trials, bringing the total number of clinical trials in operation across all therapeutic areas to 38.

CSL conducts ethical clinical trials and adheres to exemplary standards of integrity in the formulation, conduct and reporting of scientific research. This is based upon three primary elements: scientific integrity, patient safety and investigator objectivity. The CSL Clinical Quality Management System allows us to monitor and effectively oversee the quality of our clinical trials. In 2016/17, we conducted 170 internal audits (130 CSL Behring, 40 Seqirus) of our clinical trial activities, which include study site, vendor, Good Clinical Practice (GCP)/Good Laboratory Practice (GLP), pharmacovigilance, and document and system audits. In addition, 22 inspections (16 CSL Behring and 6 Seqirus) were undertaken by regulatory agencies such as the US Food & Drug Administration (FDA),

European Medicines Agency (EMA) and the Pharmaceuticals and Medical Devices Agency in Japan, to assess CSL's compliance with International Conference on Harmonization GCP (ICH-GCP) guidelines, including inspecting the clinical trials related to KCENTRA® and AFSTYLA in Japan and PRIVIGEN® in the US, as well as associated pharmacovigilance activities. All inspections confirmed adherence with GCP requirements, validated the data integrity of our clinical trials and had no impact on clinical trial licences or operations.



R&D strategy area	Number of pre-clinical and clinical studies commenced* in 16-17					Total number of clinical trials commenced in 16-17	Total number of clinical trials in operation in 16-17
	Pre-clinical†	Phase I	Phase II	Phase III	Phase IV		
Haemophilia products	1	0	0	0	1	1	7
Specialty products	0	1	0	1	0	2	7
Immunoglobulins	2	1	0	0	1	2	8
Breakthrough medicines	9	0	0	0	0	0	3
Vaccines	0	0	0	2	1	3	13
<b>TOTAL</b>	<b>12</b>	<b>2</b>	<b>0</b>	<b>3</b>	<b>3</b>	<b>8</b>	<b>38</b>

\* Defined as having a final protocol approved and study start-up activities commenced.

† Total number of GLP-toxicological studies only.

## 01 INNOVATION CONTINUED

### PATIENT SAFETY DURING CLINICAL TRIALS

Patient safety is our primary concern during all phases of our products' life cycle. Our clinical trials are carefully designed with subject safety in mind. Measures to ensure the quality and safety of subjects begins early during the design of the protocol to ensure that the appropriate patient population is selected and that the risks of participation in the clinical study do not outweigh the benefits.

Quality is built into the fabric of all clinical development activities. The foundation of quality and patient safety begins with our staff and their adherence to internal standards, which are based on global and local laws, regulations and standards. Clinical development staff are required to have routine training on global requirements and will only work with external service providers and clinical research organisations with significant experience in conducting clinical research.

The focus on quality and patient safety continues during the selection of clinical investigators. Significant efforts are made to identify physicians with experience treating patients who have the disease being studied and with experience undertaking clinical research studies. CSL requires all investigators to have evidence of training or certification on global clinical research standards, including the International Conference on Harmonisation – Good Clinical Practice (GCP).

Investigators and clinical research staff are provided with thorough training on the compound (therapy) protocol, and study specific requirements through investigator meetings, on-site visits and online training mediums, such as eLearning platforms and web-based meetings.

We minimise the risk to subjects by using appropriate exclusion criteria, by monitoring laboratory and other diagnostic parameters, and by collecting adverse events. In addition to medical monitoring of individual subjects, we analyse all emerging safety data in aggregate to identify any potential safety signals. These data are then reviewed by the safety management teams and decisions on any subsequent actions are made. Possible actions may range from escalation to other internal safety governance bodies and Data Safety Monitoring Boards to changes in the investigator brochure or the conduct of the trial.

During the study, oversight of quality and patient safety is demonstrated in several ways including routine activities such as on-site monitoring visits by clinical research associates; co-monitoring visits with CSL's representatives; data reviews by clinical research scientists and physicians, and independent data reviews by safety committees; and audits conducted by clinical quality assurance representatives. Throughout the development program, we maintain clear and transparent communication with our investigators, ethics committees, regulators and the public.

Adherence to GCP and pharmacovigilance standards during the clinical study process provides assurance that the data are of high quality, reported study results are credible and accurate, and that the rights, integrity and confidentiality of study subjects are protected.



## 01 INNOVATION CONTINUED

### 2.4 PROJECT ADVANCEMENTS / HIGHLIGHTS IN OUR STRATEGY AREAS 2016/17

#### IMMUNOGLOBULINS

CSL's immunoglobulin (Ig) portfolio continues to grow with further expansion into neurology. The US FDA accepted for review our Biologics License Application (BLA) supplement to obtain approval for a new indication for PRIVIGEN, immune globulin intravenous, 10% liquid formulation. Approval is being sought for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), a rare and progressing disease that may cause permanent nerve damage. PRIVIGEN has already been approved to treat CIDP in Europe.

Collaboration with external partners continues to provide CSL with important new opportunities to develop novel therapies for patients. In January 2017, we announced an exclusive research collaboration and worldwide licence agreement with Momenta Pharmaceuticals, Inc. to develop and commercialise their recombinant Fc multimer proteins for use in controlling inflammation. The agreement includes Momenta's novel M230 product which has been shown to match the potency and efficacy of intravenous Ig at significantly lower doses in animal models of autoimmune disease. Clinical trials using M230 are expected to start late 2017/early 2018.

#### HAEMOPHILIA AND COAGULATION PRODUCTS

Over the past year, we successfully achieved new regulatory approvals in major jurisdictions for our recombinant coagulation factor products. We received regulatory approval in Europe and Canada for AFSTYLA, the only recombinant factor VIII single chain indicated for the treatment of haemophilia A and approval in Japan is expected later this year.

Regulatory approval was granted in Japan for IDELVION, our long-acting fusion protein linking recombinant coagulation factor IX with recombinant albumin for the treatment of haemophilia B. The efficacy of our recombinant coagulation factors was highlighted during the presentation of data from our pivotal Phase III studies at the World Federation of Hemophilia 2016 World Congress in Orlando, US, in July. Preliminary results using IDELVION in the PROLONG-9FP extension trial suggest that extended treatment intervals of up to 21 days may be possible for adults. This extended regime would provide a significantly reduced burden of treatment associated with frequent prophylactic dosing and a positive impact for patients. IDELVION is currently licensed for treatment intervals of up to 14 days.

#### SPECIALTY PRODUCTS

Strong progress has been made in our specialty products portfolio over the past year. Results of a landmark study published in December 2016 confirmed the disease-modifying effect of RESPREEZA®, a highly purified alpha-1 therapy for maintenance treatment to slow the progression of hereditary emphysema in patients with alpha-1 antitrypsin deficiency (AATD). AATD is a hereditary condition resulting in a low level or absence of alpha-1-proteinase inhibitor (A1-PI), which contributes to the loss of lung structure and function. The use of RESPREEZA in the largest and longest placebo-controlled AATD trial to ever have been conducted slowed the progressive loss of lung tissue, which once lost is never recovered. The greatest benefit was observed in the "early-start" patient group, demonstrating that early intervention with RESPREEZA is key to preventing the irreversible loss of lung tissue associated with AATD.

In June 2017, the US FDA approved our BLA for a low-volume subcutaneous C1-esterase inhibitor (C1-INH) replacement therapy to prevent hereditary angioedema (HAE) attacks. HAE is a rare and potentially life-threatening genetic condition caused by a lack of or malfunctioning C1-INH protein and can lead to the build-up of fluid in multiple parts of the body. If untreated, HAE attacks involving the face or throat can result in airway closure, asphyxiation and potentially death. The FDA has granted seven years of orphan-drug exclusivity for HAEGARDA, the first and only self-administered subcutaneous prophylactic therapy to prevent HAE attacks. HAEGARDA will provide a new standard of care for HAE in adolescent and adult patients.

## 01 INNOVATION CONTINUED

### 2.4 PROJECT ADVANCEMENTS / HIGHLIGHTS IN OUR STRATEGY AREAS 2016/17

#### BREAKTHROUGH MEDICINES

Significant progress has been made in the development of new breakthrough medicines over the past year with the initiation of human trials to investigate new monoclonal antibodies with novel mechanisms of action.

CSL324 neutralises G-CSF activity and may provide a new treatment for rare inflammatory diseases associated with overactive neutrophils (white blood cells).

CSL312 is an anti-factor XIIIa monoclonal antibody that is being studied for use in multiple indications including as a subcutaneous therapy for HAE with the potential for administration once every two to three weeks. Another potential indication under investigation for CSL312 is the prevention of thrombosis.

CSL346 targets vascular endothelial growth factor B (VEGF-B) and could potentially be used to control glucose absorption in type 2 diabetics by targeting fatty acid metabolism. CSL346 may also be beneficial in the treatment of diabetic nephropathy, one of the most common kidney complications associated with type 2 diabetes, where VEGF-B levels have been shown to be elevated in patients.

Phase I clinical trials with CSL324 and CSL312 started in July and October 2016 respectively and CSL346 is due to enter the clinic in late 2017.

Positive results from our Phase IIb clinical trial designed to evaluate the safety and proof of mechanism of CSL112, a novel apolipoprotein A-I infusion therapy, were presented in November 2016. CSL112 is being developed to reduce the high incidence of early recurrent cardiovascular events that occur in the weeks to months following a heart attack by rapidly stabilising additional atherosclerotic plaques at risk of rupture. Data from the trial demonstrated that CSL112 does not cause significant changes in liver or kidney function and demonstrated that it is well-tolerated on administration in the acute myocardial infarction setting, thereby meeting the primary safety endpoints. CSL112's unique mechanism of action, the removal of cholesterol from atherosclerotic plaque in the arteries, was also confirmed by the study.

#### VACCINES AND LICENSING

The Seqirus influenza vaccine portfolio involves several late stage projects, mostly involving the development of quadrivalent versions to replace/supplement trivalent vaccines. All seasonal and pandemic influenza vaccine projects are either in Phase III or registration/launch.

The quadrivalent version of the Australian-produced AFLURIA was approved by the Therapeutic Goods Administration (TGA) in Australia and the US FDA for use in people aged 18 years and over. This vaccine will be known as AFLURIA QUAD™ in Australia, and AFLURIA® QUADRIVALENT in the US.

## 01 INNOVATION CONTINUED

### 2.5 PRODUCT REGISTRATIONS 2016/17\*

Therapy area	Product	Country/region
<b>Immunoglobulins</b> Focus on improved patient convenience, yield improvements, expanded labels, new formulation science and specialty immunoglobulins	BERIRAB® P	Azerbaijan
	HIZENTRA®	Iran, Jordan
	PRIVIGEN	Armenia, Ecuador, Egypt, Uzbekistan
	TETAGAM® P	Armenia
<b>Haemophilia and coagulation products</b> Support and enhance plasma products and develop a novel recombinant portfolio with a focus on scientific product innovation and patient benefit	AFSTYLA	Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK
	HAEMATE® P	Iraq, Tunisia, Uzbekistan
	IDELVION	Australia, Japan, New Zealand, Switzerland, US
<b>Specialty products</b> Leverage our high quality, broad specialty plasma products portfolio through new markets, novel indications and new modes of administration	ALBUREX® 20%	Peru, Uzbekistan
	BERINERT®	Malta, US
	Human albumin 20% solution	Cyprus (ALBUMEON®), Pakistan (ALBURX® 20%), Portugal (ALBUMINA HUMANA), Saudi Arabia
	HAEGARDA	US
	KCENTRA	Japan
	RIASTAP®	Malta
	ZEMAIRA®	Australia, Canada
<b>Vaccines and licensing</b> Supporting products for the prevention of infectious diseases and partnering our intellectual property	AFLURIA QUAD	Australia†
	Afluria® Quadrivalent™	US†

\* First-time registrations or indications for CSL products in the listed countries/regions over the reporting period.

† Registrations were also included in CSL's 2015/16 report due to timing discrepancies. Trademarks listed are those at time of publication.

# 03

## ENSURING THE SAFETY AND QUALITY OF OUR THERAPIES

The development, manufacture and supply of high quality and safe products is critical to our ability to continue to save lives and improve the health and wellbeing of patients with serious diseases.

## 03 ENSURING THE SAFETY AND QUALITY OF OUR THERAPIES

### GOVERNANCE

CSL is committed to providing products of superior standard to save lives and improve the outlook of patients with chronic conditions. Assuring the safety of our plasma donors and the quality of our starting materials, through to the consistent and controlled manufacture, distribution and ongoing safety surveillance of our products, is of the utmost importance to CSL.

People are the core of CSL's quality system and quality culture, and CSL takes a product lifecycle approach to the establishment of quality systems. CSL employs an integrated quality function that strives to maintain the highest standards through the use of global quality standards. These are reflected in global and local policies, and procedures as well as global and local electronic systems to support management of the quality processes.

Our product lifecycle approach includes global quality involvement or oversight of the following activities:

- Support of research and development (R&D) and clinical trial activities required to bring new products to market;
- Quality audits of and support for selection of suppliers;
- Implementation and management of quality systems at each plasma centre, distribution centre and manufacturing site;
- Trending of quality and manufacturing performance throughout the product lifecycle;
- Oversight of global logistics activities to assure the safe and compliant transfer of product to our patients; and
- Support for the critical safety and pharmacovigilance activities required to assure ongoing monitoring of product safety in the field.

Through the entire product lifecycle – from the R&D bench through to product retirement – quality staff and systems are there to support the organisation on a global basis.

### 3.1 PERFORMANCE

In 2016/17, CSL's quality systems, plasma collection and manufacturing operations were subject to 343 regulatory agency inspections around the world. These inspections resulted in no changes to our product marketing licences and provide significant evidence that the quality systems established globally by CSL are robust and in compliance with regulatory agency expectations.

The quality of CSL's end products begins with the quality of our suppliers. To supplement ongoing monitoring of supplier performance and to assure continued consistent high quality materials from our partners, CSL Behring and Seqirus conducted a combined 609 quality audits of suppliers worldwide. Efforts to enhance interactions with suppliers, at a relationship and quality perspective continue, with the established centralised and holistic global supply chain quality functions.

During the reporting period, CSL initiated four voluntary safety-related product recalls. The first, initiated in August 2016 at the direction of the product manufacturer, Bayer, was the recall of HELIXATE<sup>®</sup>, antihemophilic factor (recombinant), in multiple countries due to substandard shelf-life potency. The second recall, in September 2016, was initiated by CSL in response to evidence of counterfeit activities which were investigated in relation to CSL's albumin product in Mexico. While CSL

had no quality concerns with any legitimate product in the marketplace, we took proactive measures to remove product from the market to minimise the potential for counterfeit product to reach our patients. In February 2017, CSL initiated a safety-related recall which was triggered by a product potency labelling error for RESPREEZA<sup>®</sup>, a maintenance treatment for severe alpha-1 antitrypsin deficiency, which was distributed in France. Finally, Seqirus recalled, in the form of written notification to users only, both PHENOCELL<sup>™</sup> B and ABTECTCELL<sup>™</sup> III, in vitro diagnostic medical devices, in Australia, due to lower-than-expected responses provided during use in certain test methods.

CSL's global counterfeit management policies continue to provide prompt responses to reports of counterfeit products. In 2016/17, CSL investigated three counterfeit product reports from two countries. All of these reports, which were investigated in conjunction with local law enforcement and health authorities, were found to be counterfeit.

Over the reporting year, under the lead of CSL's Global Clinical Safety and Pharmacovigilance (GCSP) function, multiple audits and inspections by regulatory agencies (e.g. French Agency for the Safety of Health Products) consistently confirmed the robustness of CSL's pharmacovigilance system.



## 03 ENSURING THE SAFETY AND QUALITY OF OUR THERAPIES CONTINUED

### 3.2 SAFETY AND THE MANUFACTURE OF OUR PLASMA THERAPIES AND VACCINES

In December 2015, CSL Behring introduced Ig IsoLo®, an immunoaffinity chromatography step, into the manufacturing process of PRIVIGEN®, proline stabilised 10% immune globulin (Ig), and HIZENTRA®, 20% subcutaneous Ig, product, in both the Bern, Switzerland, and Broadmeadows, Australia, facilities. This additional purification step reduces anti-A and anti-B isoagglutinin antibodies originating from human plasma, therefore minimising the risk of infusion-related haemolysis in patients due to the destruction of type A, B or AB red blood cells. Ig IsoLo has now been approved by health authorities in 75 countries, including Australia, Canada, Europe, Switzerland and the United States (US), enabling the introduction of this innovative production step into their manufacturing of PRIVIGEN and HIZENTRA.

Over the reporting period, a significant focus for the Seqirus group continues to be the integration of the Novartis acquired influenza vaccine business. Teams from across the organisation worked to establish and implement a number of electronic systems supporting the fully established Seqirus Quality Management System which provides quality oversight, assurance and control of all the Seqirus Good Manufacturing Practice (GMP) processes. In 2017, Seqirus launched the new independent global safety database which includes central processing of all the reported adverse events for Seqirus products. The overall process has now been fully established under Seqirus with a fully operational independent safety team.



### PHARMACOVIGILANCE EFFORTS

Over the reporting year, under the lead of CSL's global clinical safety and pharmacovigilance (GCSP) function, cross-functional understanding and interplay regarding CSL's pharmacovigilance system has further deepened. Compliance metrics have been kept at high levels or increased. Multiple audits and inspections by regulatory agencies, such as the French Agency for the Safety of Health Products, consistently confirmed the robustness of CSL's pharmacovigilance system. In addition, we continue to enhance our technology platform with emphasis on signal detection and evaluation as well as deepening the cooperation with regional counterparts, particularly in Japan, allowing for smooth product registration submissions in this region. We further improved efficiency by process streamlining and controlled outsourcing, and built structure, skills and processes for products in early development to fully support our pipeline from first-in-human studies and onwards.

## 03 ENSURING THE SAFETY AND QUALITY OF OUR THERAPIES CONTINUED

### PLASMA DONATIONS AND DONORS

CSL Plasma prides itself on holding true to our promise to provide exemplary customer service to all our donors. This is because we recognise that donors and their plasma donations are an integral part of helping keep our promise to patients who depend on our life-saving therapies. It goes without saying that if there were no or not enough donors willing to give their time and plasma, the quality of life of patients who depend on plasma-derived products would be negatively impacted.

Post donation, each donor is given the option to anonymously provide feedback on their donation experience, customer service and likelihood to donate again or refer a friend. Once the donor completes the survey, the information is then aggregated in our donor relationship management tool. The tool allows us to analyse the performance at each centre as well as regionally and nationally.

Over the reporting period, 960,000 surveys were completed by our donors of whom 99.4% stated they would be willing to donate again and 96.5% stated they would be willing to refer a friend to donate at CSL Plasma.



More information on our promise to donors and donor safety is available on our website <http://corporateresponsibility.csl.com.au>

### INFLUENZA VACCINE MANUFACTURING INNOVATION

The introduction of cell-based influenza vaccine technology represented one of the most significant advancements in the history of influenza vaccine production. In July 2017, Seqirus announced the next major advancement in the use of this technology at its state-of-the-art manufacturing facility in Holly Springs, North Carolina, US.

Twice each year, the World Health Organization (WHO), the five WHO collaborating centres (including the Centers for Disease Control and Prevention) and their public health partners work together on the preparation of candidate virus vaccines (CVVs) – influenza viruses that are provided to manufacturers prior to every season for the production of influenza vaccines.

Last year, WHO began to also recommend cell-derived CVVs and the US Food and Drug Administration (FDA) issued an approval for Seqirus to use these CVVs in the manufacture of its influenza vaccines. The process of creating cell-based influenza vaccines involves several steps. Following WHO's recommendation of CVVs for distribution, Seqirus inoculates the CVVs into cultured mammalian cells instead of into eggs, and allows them to replicate.

The virus-containing fluid is collected from the cells, the virus antigen is purified, and the manufacturing process continues with formulation and testing. Finally, the vaccines are packaged and approved prior to release and shipment.

In an industry first, Seqirus used a cell-derived H3N2 CVV in the production of FLUCELVAX QUADRIVALENT®, quadrivalent influenza vaccine, for the 2017/18 Northern Hemisphere season, making the production of this particular strain exclusively cell-based.

Cell-derived CVV's may be more similar to circulating viruses than egg-derived CVVs, potentially improving the effectiveness of the vaccine.



## 03 ENSURING THE SAFETY AND QUALITY OF OUR THERAPIES

### CONTINUED

#### 3.3 SUPPLIER MANAGEMENT

In 2016/17, CSL Behring further embedded critical supplier management across the business, with a greater focus on medical devices and the equipment and engineering suppliers supporting our capital expansion projects. In manufacturing operations, the global sourcing team continued to closely monitor suppliers' risk profiles through the Global Risk Management Framework, and modify mitigation actions where required. These include qualification of alternative suppliers, maintaining safety stock and rigorous supplier relationship and performance management.

Relationships with CSL's critical suppliers continue to evolve in the areas of risk and innovation as we work together to support the growth of our business. Sourcing in collaboration with the supplier quality team ensure the required level of quality and performance is demonstrated consistently across the CSL business. The focus on consistency removes variation for suppliers thus simplifying their efforts to support CSL and further reduces risks and inefficiencies in our operations.

As capacity expansion projects mature and our manufacturing network becomes more globally interconnected, CSL is working with its suppliers to ensure continuity of supply and to proactively mitigate any risks associated with increased demand. This critical work is focused on needs stretching out five to ten years.

Over the reporting period, CSL commenced a global transformation initiative, PACE, that will align processes and systems across the organisation. For supplier management, PACE will be further expanding sourcing capabilities by hiring additional staff with deep category experience to enable a greater level of interaction with our suppliers. Additionally, PACE will provide processes to more effectively assess supplier compatibility to CSL's needs and to determine risk exposures before a new relationship begins. These processes will amongst other things cover financial, Code of Responsible Business Practice (our Code), quality and general business expectations we have for our suppliers.

The team established to align supplier assessment and qualification activities relating to performance against our Code, environment, health and safety matters, and quality audits continues to make progress.

In 2016/17, CSL conducted 609 quality audits of our suppliers across CSL Behring, CSL Plasma and Seqirus. This level of effort reflects our continued focus on understanding our suppliers across our value chain. In addition, over the reporting period, all (51) employees with responsibility for undertaking site audits of third parties, such as suppliers, undertook online training on Protecting Human Rights in the Supply Chain.



#### 3.4 COUNTERFEIT MEDICINES

Over the reporting period, CSL's global counterfeit management processes continued to provide prompt responses to reports of counterfeit products. CSL investigated three counterfeit product reports from two countries. All cases were investigated in conjunction with local law enforcement and health authorities, were found to be counterfeit.

CSL has developed a supply chain security management system that combines product and security requirements together with loss prevention practices and anti-counterfeiting measures, which establish protections throughout our supply chains. Any CSL or business partner facility engaged in the collection, manufacture, storage, handling or shipment of raw or ancillary materials, products or product data and assets must develop and implement a risk-based, comprehensive and documented supply chain security management system.





# 04

## OPERATING RESPONSIBLY IN THE MARKETPLACE

CSL's marketplace is diverse and complex, presenting many opportunities and challenges. Responsible conduct in the marketplace protects our reputation and sustains organisational growth.

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

#### GOVERNANCE

CSL's Code of Responsible Business Practice (our Code) underpins our approach to operating with the highest integrity in the marketplace. Market practices are governed by company-specific policies and procedures, internal compliance mechanisms and control systems that are overseen by CSL's Audit and Risk Management Committee of the Board and the Global Compliance Committee (GCC).

Comprised of members of the Global Leadership Group (GLG) and other senior executives, CSL's GCC provides strategic direction for CSL's compliance activities as well as providing a means to monitor compliance globally. The GCC oversees and supports the creation, implementation and monitoring of global compliance structures and policies and procedures to ensure business is conducted in accordance with relevant laws and regulations. This includes setting annual requirements for global compliance-based training.

#### 4.1 PERFORMANCE

In 2016/17, through supplier payments, employee wages and benefits, shareholder returns, government taxes and community contributions, CSL distributed over US\$6.9 billion in direct value to economies in which we operate, a significant increase on the previous year.

CSL remains active in public policy debates across key markets. In Australia, we made submissions to a number of State and Federal Government inquiries, including efforts to reform research and development tax incentives and employee working visas. In Europe and the United States (US), we continue our efforts to raise awareness and improve access to influenza vaccine, rare disease therapies and orphan drugs. Over the reporting period, CSL's non-partisan political contributions in Australia and the US totalled US\$33,448.

In 2016/17, there were no findings against CSL relating to a breach of any fair trading or competition laws. Furthermore, over the reporting period, no breaches were found by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) or Medicines Australia with respect to the marketing and promotion of our medicines.

#### CSL'S ECONOMIC PERFORMANCE<sup>a</sup>

Assessing economic performance at CSL is integral to the delivery of our strategy. The Commercial Operations Senior Leadership Team oversees the delivery of our marketplace strategy and is responsible for sales and marketing, the identification of new markets and targeted patient support in the community. The CSL Board has strategic oversight and monitors performance through key sub-committees.

	14-15 US\$million	15-16 US\$million	16-17 US\$million
<b>DIRECT ECONOMIC VALUE GENERATED</b>			
Total revenue	5,628	6,129	6,934
<b>DIRECT ECONOMIC VALUE DISTRIBUTED</b>			
Operating costs	2,874	3,678	4,162 <sup>b</sup>
Employee wages and benefits	1,213	1,346	1,574
Payments to providers of capital (e.g. dividends)	593	649	690
Payments to government (tax) <sup>c</sup>	329	425	483
Total	5,009	6,098	6,909
<b>ECONOMIC VALUE RETAINED</b>	<b>619</b>	<b>31</b>	<b>25</b>

<sup>a</sup> Prepared in accordance with the Global Reporting Initiative's (GRI's) Sustainability Guidelines Version 4 (other than payments to government - see c below). Incorporates financial data for the GSL Group, including CSL Behring and Seqirus.

<sup>b</sup> In 2016/17, CSL contributed US\$40.0 million towards global community efforts.

<sup>c</sup> Includes only corporate tax paid at the international, national and local level.

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

#### 4.2 FAIR COMPETITION

CSL's GCC is responsible for providing strategic direction to CSL's fair competition compliance activities and monitoring the implementation and evolution of global fair competition compliance initiatives. We ensure fair competition across all geographies and business units by advocating a culture involving the strict exclusion of practices that would mislead consumers, contravene applicable trade practices or competition laws, or constitute unfair practices. CSL seeks to avoid any breaches of regulations or industry codes of conduct by recognising the importance of competing fairly in the global marketplace and ensuring equitable access to patient therapies and vaccines.

In 2016/17, there were no findings against CSL relating to a breach of any fair trading or competition laws.

#### 4.3 INTERACTIONS WITH GOVERNMENT

Governments play a critical role for the healthcare industry, specifically with the development of reimbursement frameworks and product access regimes across CSL's entire value chain. CSL recognises the importance of participating in political and public policy matters that directly impact business operations. Public policy initiatives are primarily focused in Australia, Asia, Europe and North America, where appointed senior personnel are responsible for engaging with governments and other key stakeholders on public policy matters. CSL engages directly with governments and through active membership in industry groups. The company also contributes to public policy through engagement with patient organisations and public health agencies at a national and global level.

##### In Australia:

- CSL has continued to engage with the Australian Federal Government in relation to the ongoing review of the existing research and development (R&D) tax incentive. CSL has provided both written evidence and participated in various verbal consultations with the Minister for Industry and the Minister for Health. CSL has submitted that reducing or restricting the incentive may result in a reduction of onshore R&D.

- CSL has also participated in consultations with the Victorian State Government in relation to their vision for advanced manufacturing in the state and with the Australian Federal Government's Office of Innovation and Science Australia in relation to their 2030 Vision for the sector.
- CSL was an active participant in advocacy around announced changes to Australia's skilled migration program. Unchanged, the planned amendments would have severely restricted CSL's ability to fill skills gaps and access international talent. CSL's position was that Australia needs a visa system that encourages utilisation and professional development of local employees but that also allows companies access to international talent where it assists the transfer of skills and knowledge and supports businesses to operate at a world-class standard. Fortunately, the Federal Government reversed a number of the foreshadowed changes on 1 July 2017.

##### In Europe:

- As a member of the European Plasma Protein Therapeutics Association (PPTA Europe), CSL Behring contributed to a constant dialogue with the European Commission for consideration of whether and how modifications to the European Blood Directive should be enacted. In particular, CSL Behring contributed to the political evaluation of the current legislation though the European Commission's public consultation launched in May 2017 and the preparation of PPTA's recommendations for a revision of the current framework. CSL Behring likewise contributed to PPTA's interaction with the World Health Organization (WHO) and the Council of Europe (Committee on Bioethics) with regard to initiatives on donor compensation ethics.
- CSL Behring's public policy efforts, in concert with European trade associations, were targeted at maintaining a supportive environment for innovation in rare disease therapies and orphan drugs. There are growing challenges in securing patient access to new orphan drugs, largely due to budgetary constraints of member states. We advocated that new policy initiatives should aim to establish Health Technology Assessments (HTA) and value assessment approaches that would streamline and accelerate patient access across different countries and have measures appropriate for these critical rare disease therapies.

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

- As a member of the industry trade association European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), CSL Behring has collaborated with European multi-stakeholder expert group ORPH-VAL, consisting of patient representatives, physicians, academics, HTA practitioners, politicians and pharmaceutical industry representatives. In February 2017, ORPH-VAL published a new set of common principles to improve the consistency of decision-making for orphan drugs and balance the needs of innovators and payers.
  - EURORDIS, the European rare disease patient umbrella organisation, and partners brought together industry, patient leaders, academics, regulators and payers in a multi-stakeholder symposium in February 2017 to discuss the current state of play and how to shape a more effective way to address value determination, appraisal, pricing and reimbursement of orphan medicines. This symposium was aimed at improving patients' access to rare disease therapies throughout Europe and was connected to the annual international Rare Disease Day 2017. CSL Behring supports the development of the effort and program and served as session rapporteur.
  - CSL Behring is working in cooperation with politicians and governmental authorities in different European countries on developing healthcare management tools for patients with rare diseases. In Germany, in cooperation with the Federal Joint Committee (G-BA, the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany) and health insurance companies, we are developing a healthcare economic concept of a high-cost treatment budget which can secure the financing of diagnostics and treatment of rare diseases.
  - Seqirus increased policy advocacy in Europe this year, focusing on issues related to influenza vaccine recommendations, coverage and effectiveness. In September 2016, Seqirus made a submission to a UK Government inquiry into the implications of Brexit for science and research, highlighting potential issues that are unique to the supply of seasonal and pandemic influenza. The company also participated in various industry consultations and advocacy on Brexit issues, particularly with regard to implications for the regulation of medicines.
  - As an active member in Vaccines Europe, Seqirus participated in priority setting for the European Parliament on Joint Action on Vaccination (JAV) and the development of an evidence-based influenza vaccine manifesto to raise awareness about the social and economic burden of influenza in European countries. JAV seeks to develop a framework for cooperation and strategies to address issues related to vaccination and preparedness.
  - Seqirus was also part of a public private partnership that was successful in obtaining funding from the Innovative Medicines Institute to develop a sustainable study platform for the conduct of vaccine brand-specific effectiveness studies. The partnership, called the Development of Robust and Innovative Vaccine Effectiveness (DRIVE), brings together the influenza vaccine industry and public health institutes and government agencies from across Europe to enhance the approach to influenza effectiveness studies and to meet new regulatory requirements.
- In North America:**
- CSL Behring is actively engaging with the US Congress as it considers major tax reform. We support efforts in Congress and in the administration to reduce the US corporate tax rate, among the highest in the world, but are engaged in defending certain existing important tax policy provisions that are being considered for elimination or modification to fund tax reform. These include preservation of the orphan drug tax credit, which fosters investment in rare disease therapies. We also have worked to obtain available tax credits at the local plant level that recognise the investment that we are making in manufacturing plants.
  - CSL Behring has also been very involved regarding the potential modification of the US Affordable Care Act, advocating to maintain patient protections for the populations that we serve, as well as removing negative fees on pharmaceuticals and devices.
  - Within the 21st Century Cures legislation, which provided additional funding for US research, CSL Behring successfully advocated for the elimination of a bid program for drugs administered through Durable Medical Equipment, such as an infusion pump. The bid program likely would have resulted in limited therapeutic choices for patients.

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

- In tandem with patient groups and medical providers, CSL Behring was part of the larger biotech industry effort that successfully defeated an Obama administration proposal to reduce Medicare drug reimbursement for healthcare providers. If this change had been enacted, it would have impacted patient access to life-saving therapies for Medicare beneficiaries, including those using CSL Behring therapies.
- CSL Behring has advocated for legislation that would remove unnecessary provisions that add to the cost of plasma collection. For example, legislation was achieved in the state of Georgia exempting plasma collection from certain state requirements that really did not contribute to safety, while legislation is proceeding through the California legislature appropriately tailoring the staffing requirements for administering a total protein test.
- CSL Behring partnered with bleeding disorder organisations to mitigate step therapy proposals to ensure patients have access to multiple brands of therapy.
- CSL Behring has led efforts in multiple states to preserve appropriate reimbursement for blood clotting factors to ensure patients have access, most notably in California.
- In the province of Ontario, Canada, CSL Behring and six provincial hospitals have been engaged in an ongoing effort with the Health Ministry to promote the creation of a pilot project where the ministry would fund nursing services associated with the administration of subcutaneous immunoglobulin, which would improve care and access, and reduce overall treatment costs. The Health Ministry decided to support the program and cosponsored the proposal with the Ottawa Hospital for review before the Ontario Health Technology Advisory Committee (OHTAC), which is the province’s health technology assessment board where approval is needed. The OHTAC agreed that the proposal would reduce overall cost for primary immunodeficiency while increasing health benefit, and the program is advancing.
- Seqirus is actively engaging with US Congress on immunisation prevention. Efforts include engagement on legislation and appropriations supportive of both seasonal influenza and pandemic preparedness. Engagement is done directly and through two industry organisations: Biotechnology Innovation Organization (BIO) and the Alliance for Biosecurity.

At a global level, this year Seqirus became a full member of the International Federation of Pharmaceutical Manufacturers Association (IFPMA) as part of our commitment to have greater policy engagement with international agencies focused on public health and economic development.

Seqirus also continued its long-standing commitment to pandemic preparedness policy through collaboration with WHO and other industry partners involved in the IFPMA Influenza Vaccines Supply Taskforce. Working with partners to achieve greater transparency of the priorities, programs and expenditures of the WHO Pandemic Influenza Preparedness Framework was the major focus of Seqirus’ advocacy this year.

### POLITICAL ENGAGEMENT

CSL undertakes financial contributions to political parties and candidates as part of engaging in the political process and ensures compliance with specific jurisdictional laws and regulations as relevant. In addition, political contributions are made in accordance with global and local authorisation levels.

Over the reporting period, CSL contributed a total of US\$33,448.17\* to political organisations in Australia and the US. This amount comprised support for candidates in US state-based elections, and in Australia, contributions towards attendance at political party conferences, roundtables and/or fundraising events (such as breakfast briefings, luncheons or dinners). In all other regions, CSL made no political contributions.

CSL also provides for the administrative costs of a political action committee (PAC), whereby eligible employees in the US voluntarily contribute to the PAC to provide contributions to political candidates who support patient care and policies to enhance biopharmaceutical innovations. The PAC is run by an employee PAC Board and is fully compliant with US election laws and reporting requirements.

### POLITICAL CONTRIBUTIONS

Country	Contribution
US	US\$5,200
Australia	A\$37,568.89

\* When converted to US currency and excludes operations acquired from the Novartis influenza vaccine business.

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

#### 4.4 ANTI-BRIBERY AND ANTI-CORRUPTION

CSL operates in a diverse and complex marketplace where bribery and corruption are risks that could expose the company and employees to possible prosecution, fines and imprisonment. CSL has a number of commercial arrangements with governments and related agencies across various geographies, presenting both challenges and opportunities to the organisation.

We consider our overall risk relating to corruption to be low and are committed to ensuring full compliance in how we conduct our operations across all regions in which we operate and are seeking to enter.

Over the reporting period, CSL reviewed and published a third edition of our Code, setting the foundation for our expectations of employees and third parties. Furthermore, we updated and reissued other related global policies – Provision of Gifts, Entertainment and Hospitality, and Interactions with Healthcare Professionals and Healthcare Organisations – which provide further guidance to employees. Such guidance includes acceptable limits for expenses incurred in connection with company business, and establishes a formal approval process by senior management for certain expenses over a prescribed amount (or such lower amount as may be set in a particular country by local management).

In addition, over 2016/17:

- 92% of CSL employees undertook Global Anti-Corruption training delivered by our global learning management system partner;
- Our operations conducted a biannual assessment of bribery and corruption risk within their businesses. This is achieved by means of a standardised questionnaire that is completed and the responses are then reviewed by the GCC. In 2016/17, these assessments did not identify any significant corruption risks; and
- Our global hotline process revealed no instances of bribery or corruption.



#### 4.5 ACCESS TO MEDICINES

CSL is committed to ensuring that pricing for our products is done in a responsible manner, for both patients and investors. Pricing is a key factor amongst a number of other considerations that can significantly impact patient access in both developed and developing markets. Prices of medicines reflect the clinical value to patients, communities and governments and provide an economic basis for future investment into the development of new therapies.

In 2016/17, CSL provided a number of therapies to 35 low-to-middle-income countries (as classified by the World Bank at August 2017). Access to these therapies is either through a local distributor in response to a competitive tender or via direct arrangement with governments or non-government organisations (NGOs). In addition, across our key therapy areas, CSL's long-standing partnerships with patient groups and non-government organisations help to improve access to our therapies in developing countries (see page 43 for more).



## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

#### VALUE VERSUS COST

What is often missing in statements about the cost of medicines and in proposed solutions is an answer to the fundamental question, “What is the value of pharmaceutical products to patients and the healthcare system versus the cost?” Maintaining a singular focus on drug cost outside the context of value and facts, we risk constraining the growth of R&D, effectively damaging the innovation ecosystem that has delivered and holds the greatest promise for patients.



Innovative medicines are helping to prevent the costly complications of untreated primary immunodeficiency (PI), as evidenced by a survey of physician-experts at the Jeffrey Modell Centers Network. The results of this study showed significant reductions in acute and chronic infections, pneumonias, hospital and emergency room visits, days on antibiotics, days in the hospital, and school and work days missed, after proper diagnosis and treatment of patients with PI. It showed that an undiagnosed patient with PI costs the healthcare system, families and society an average of nearly US\$110,000 per year, which can be avoided with treatment, not to mention the overarching value to patient quality of life and wellbeing.<sup>1</sup>



According to the National Hemophilia Foundation, the average life expectancy of a person with haemophilia in 1960 was less than 20 years. Today, the use of factor therapies manufactured by CSL Behring and others to treat this condition means that children with haemophilia can now look forward to a normal life expectancy.<sup>2</sup>



Drugs have effected tremendous reductions in healthcare expenditures that far exceed the costs of medicines. Better adherence to medicines alone could save over US\$200 billion per year in healthcare expenditures in the US according to IMS Health data.<sup>3</sup>



In the pharmaceutical industry, developing a new medicine from drug discovery through US FDA approval takes 10 years on average and costs around US\$2.6 billion. Moreover, only 12% of the medicines that make it into Phase I clinical trials will be approved by the FDA.<sup>4</sup>

CSL continues to engage with decision-makers on the value of therapies and what is needed to sustain a pro-innovation environment to foster the continued creation of these therapies that are so important to patient wellbeing and healthcare delivery.

- 1 Modell, V., Gee, B., Lewis, D.B. et al., “Global study of primary immunodeficiency diseases (PI) – diagnosis, treatment, and economic impact: an updated report from the Jeffrey Modell Foundation”, *Immunologic Research* (2011), 51: 61, <https://rd.springer.com/article/10.1007%2Fs12026-011-8241-y> (accessed 2017).
- 2 “History of Bleeding Disorders”, National Hemophilia Foundation, [www.hemophilia.org/Bleeding-Disorders/History-of-Bleeding-Disorders](http://www.hemophilia.org/Bleeding-Disorders/History-of-Bleeding-Disorders) (accessed 2017).
- 3 “Avoidable Costs in US Healthcare”, IMS Institute for Healthcare Informatics, June 2013, [www.imshhealth.com/files/web/IMSH%20Institute/Reports/Avoidable\\_Costs\\_in%20\\_US\\_Healthcare/IHII\\_AvoidableCosts\\_2013.pdf](http://www.imshhealth.com/files/web/IMSH%20Institute/Reports/Avoidable_Costs_in%20_US_Healthcare/IHII_AvoidableCosts_2013.pdf) (accessed 2017).
- 4 “Biopharmaceutical Research & Development: The Process Behind New Medicines”, PhRMA, 2015, [http://phrma-docs.phrma.org/sites/default/files/pdf/rd\\_brochure.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure.pdf) (accessed 2017).

## 04 OPERATING RESPONSIBLY IN THE MARKETPLACE

### CONTINUED

#### 4.6 RESPONSIBLE MARKETING OF MEDICINES

Responsible marketing of prescription medicines is vital to maintaining consumer trust in the pharmaceutical industry and ensuring patients receive the maximum benefits from our products and services. Government regulation and industry codes oversee the marketing of our medicines, vaccines and therapies across key regions where we operate.

During 2016/17, neither Seqirus Australia nor CSL Behring Australia were found to be in breach of the Medicines Australia Code, where CSL is a signatory. For international operations, CSL (including CSL Behring and Seqirus) was not found to be in breach of any regulation of the US FDA or the EMA with respect to the promotion or marketing of medicines, vaccines and therapies.

#### 4.7 DATA PROTECTION AND PRIVACY

CSL views data protection and privacy as a key component of corporate sustainability. CSL collects and holds personal information about our employees and key stakeholders, such as plasma donors, healthcare professionals and patients. Unauthorised access or use of this information presents a risk to our operations, and CSL's place as a leader in the biotherapies marketplace.

We have taken substantive efforts to protect our patients', donors' and employees' personal information through the broader use of data handling process improvement and encryption. In addition, we comply with relevant privacy and health regulations in all jurisdictions where we operate and are committed to safeguarding the privacy of personal information that we gather.

CSL continues to manage cybersecurity events using a risk-based approach resulting in the management of cyber risk without the known loss of information or business continuity.

Security awareness is a top priority and each year we provide mandatory security awareness training for all employees and contingent workers. In 2016/17, 93% of CSL employees undertook Global Information Security: Safeguarding Company Information training delivered by our global learning management system partner.





# 05

## SUPPORTING OUR COMMUNITIES AROUND THE WORLD

CSL believes that supporting local and global communities helps to build healthier and more sustainable environments. Our global community contributions framework guides our support and focus areas, helping to drive shared value for CSL and our stakeholders.

## 05 SUPPORTING OUR COMMUNITIES

### GOVERNANCE

CSL's approach to community contributions is guided by our Code of Responsible Business Practice and Global Community Contributions Policy. The policy applies to all CSL companies and employees and is intended to be implemented across the businesses to guide decision-making and management of any form of community contribution, financial or by other means. The core of the policy is our community contributions framework, which sets out our key focus areas of support.



### 5.1 PERFORMANCE

In 2016/17, CSL contributed US\$40 million to patient, biomedical and local communities, a significant increase on prior years, largely due to Seqirus' US\$3.7 million contribution to the World Health Organization (WHO) and increases across other contribution areas. . Our support for patient communities continues as a priority, with the majority of total funding directed towards programs that enhance patient quality of life and improved access to our medicines.

To this end, CSL Behring maintained its long-standing support of the international haemophilia community, contributing more than four million units of coagulation factor to the World Federation of Hemophilia (WFH). We also extended our existing support for the Jeffrey Modell Foundation by sponsoring the North African Network, which is establishing diagnostic and research centres in Algiers, Morocco, Egypt and Tunisia. Additionally, Seqirus contributed significant funding to the Pandemic Influenza Preparedness (PIP) Framework and made a commitment to the WHO to donate 10% of real-time influenza vaccine production to developing countries in the event of a pandemic.

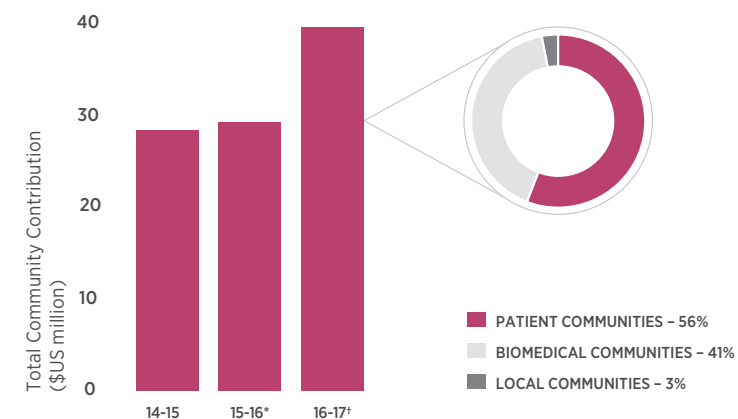
For biomedical communities, CSL supported 51 independent investigator-initiated studies to help advance scientific knowledge and improve patient outcomes. Programs, such as the CSL Young Florey Medal, the CSL Behring Heimburger Awards in Germany and the inaugural CSL Centenary Fellowships, recognised excellence in biomedical research and helped to encourage the best and brightest to further medical research.

Regionally our sites provided employees with community engagement activities, seeking to support local needs and the disadvantaged while creating a sense of employee pride in the workplace and the organisation.

### CSL'S GLOBAL COMMUNITY CONTRIBUTIONS FRAMEWORK

SUPPORT FOR PATIENT COMMUNITIES	
<ul style="list-style-type: none"> <li>• Enhancing quality of life for patients in the conditions our therapies treat</li> <li>• Improving access to our biological medicines</li> </ul>	Aligns with CSL's Values of Patient Focus & Integrity Supports CSL's growth strategic objective by improving patient outcomes
SUPPORT FOR BIOMEDICAL COMMUNITIES	
<ul style="list-style-type: none"> <li>• Advancing knowledge in medical and scientific communities</li> <li>• Fostering the next generation of medical researchers</li> </ul>	Aligns with CSL's Values of Innovation & Collaboration Supports CSL's innovation strategic objective by fuelling new breakthroughs, enhancing scientific knowledge and building capability and capacity
SUPPORT FOR LOCAL COMMUNITIES	
<ul style="list-style-type: none"> <li>• Supporting community efforts where we live and work</li> <li>• Supporting communities in times of emergency</li> </ul>	Aligns with CSL's Value of Superior Performance Supports CSL's workplace culture strategic objective by creating an environment that employees feel proud to perform within

### CSL'S GLOBAL COMMUNITY CONTRIBUTIONS



\* Excludes operations acquired from the Novartis influenza vaccine business.

† Includes a limited number of patient organisation contributions undertaken by the Novartis influenza vaccine business.

## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### 5.2 SUPPORTING PATIENT COMMUNITIES

#### ENHANCING THE QUALITY OF LIFE FOR PATIENTS

For CSL, a focus on patients is a priority and promise. In 2016/17, CSL contributed US\$12.5 million to local, national and international organisations to assist with patient support and education, disease awareness, early diagnosis, medical research and advocacy efforts.

We have collaborative relationships with patient groups around the world, such as the European Organisation for Rare Diseases and the US National Organization for Rare Disorders. On regional and market levels, we support numerous patient groups that seek to improve quality of life outcomes for patients.

In 2017, Seqirus supported programs organised by the Immunization Action Coalition (IAC) and the National Foundation for Infectious Diseases (NFID) in the United States (US), and the European Scientific Working Group on Influenza (ESWI). These educational programs were concentrated around the topic of vaccination against influenza, with a focus on the protection of patients of all age ranges, from paediatric to adults aged 65 and over.

#### SUPPORTING PATIENT COMMUNITIES 2016/17



BREAKDOWN OF TOTAL PATIENT COMMUNITY CONTRIBUTIONS

- PATIENT ORGANISATION SUPPORT – 55%
- PATIENT ASSISTANCE/HUMANITARIAN ACCESS PROGRAMS – 45%



#### CONNECTING WITH PATIENTS AND RAISING AWARENESS

In June 2017, CSL Behring launched a new product in the US. HAEGARDA® is the first and only subcutaneous therapy for preventing hereditary angioedema (HAE) attacks. HAE is a rare, genetic and potentially life-threatening condition that causes painful, debilitating and unpredictable episodes of swelling of the abdomen, face, larynx and extremities, among other areas of the body. This year, our commitment to the HAE community has never been stronger with CSL Behring’s support for the US Hereditary Angioedema Association’s (HAEA) 5K run/walk series, HAE-In-Motion®.

HAE-In-Motion 5K events are the largest national fundraising platform for HAEA, consisting of 11 five-kilometre run/walks

in 2017. Through this program, HAEA encourages patient community participation to raise awareness while helping HAE patients achieve lifelong health.

HAEA explains that the name HAE-In-Motion portrays the fundamental pillars of its commitment to improving the lives of HAE patients – increasing the momentum of research efforts, the mile markers crossed in realising treatments to help HAE patients lead normal lives, and the strides toward finding a cure.

Each walk gives CSL Behring the opportunity to connect with patients, caregivers, healthcare professionals, family and friends, who are coming together in support of HAE patients.

## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### IMPROVING ACCESS TO OUR BIOLOGICAL MEDICINES

CSL continues to work with international and national partners to deliver life-saving therapies to patients across the world. Our longstanding partnerships with the World Federation of Hemophilia and the Jeffrey Modell Foundation continue to be strong (see page 37 for more information on our support for improved access).

In 2017, Seqirus also contributed US\$3.7 million to the WHO Pandemic Influenza Preparedness Framework, which aims to enhance program infrastructure and pandemic readiness in low and middle-income countries.

In addition, over the reporting period, CSL Behring provided US\$5 million in product and/or financial support directly to US patients through our patient assistance programs. These access programs support qualified patients who are uninsured, underinsured or cannot afford their prescribed therapy.

### PARTNERING TO IMPROVE DIAGNOSIS AND ACCESS ACROSS OUR THERAPY AREAS

#### Haemophilia

CSL marked World Hemophilia Day in April 2017 by contributing more than four million international units (IUs) of treatments for haemophilia A and/or von Willebrand disease. The contribution is part of CSL Behring's three-year promise to provide more than 10 million IUs of specialty biotherapeutics to the World Federation of Hemophilia (WFH) to treat haemophilia in the developing world. In 2016, CSL Behring's product donations to the WFH supported haemophilia patients in Cambodia, Cameroon, Jamaica, Mali, Nicaragua, Philippines and Venezuela.

#### Primary immunodeficiency

The Jeffrey Modell Foundation is devoted to early and precise diagnosis, meaningful treatments and, ultimately, cures for those with primary immunodeficiency (PI). CSL Behring has been a partner to this organisation and their important work of creating PI diagnostic and research centres since its inception over 30 years ago. In March 2017, the foundation announced its plans to open its first PI network and centre in Africa, with CSL Behring a proud sponsor. The North African Network will join over 200 similar sites in the Jeffrey Modell Centers Network around the world. These centres offer advanced diagnostic evaluation to patients with a suspected primary immune deficiency and our support helps CSL to deliver on our promise to PI patients. In Africa, it's estimated that the diagnosis rate of PI, a life-threatening condition, is only about 0.3%.

#### Influenza

As part of our global commitment to access and benefit sharing of influenza viruses, Seqirus has agreed to donate 10% of influenza vaccine output in real time to WHO for deployment to developing countries in the event of a global pandemic emergency. Seqirus also contributed US\$3.7 million to the WHO Pandemic Influenza Preparedness Framework, which aims to enhance program infrastructure and pandemic readiness in low and middle-income countries.

## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### 5.3 SUPPORTING BIOMEDICAL COMMUNITIES

CSL supports biomedical communities in a variety of ways, including through active participation in education and development programs and the support of biomedical research.

#### EDUCATION AND DEVELOPMENT

We believe development and education programs, including support for biomedical conferences and symposia, are critical for advancing scientific knowledge and encouraging the best and brightest students to pursue and remain in medical research careers.

Over the reporting period, CSL continued its support of longstanding initiatives that seek to inspire careers, encourage the most promising science and medical students and recognise excellence in biomedical research (see the following table, in which key programs are highlighted).

#### UNDERGRADUATE RESEARCH OPPORTUNITIES PROGRAM

In February 2017, CSL announced that it will continue to sponsor the Undergraduate Research Opportunities Program (UROP) for another three years. UROP is a skills development scheme run by Biomedical Research Victoria, Australia. CSL proudly contributes A\$100,000 per year to the program in support of the next generation of scientists. Since 2009, CSL has been a principal sponsor of UROP, which has seen more than 300 undergraduate students access casual employment in eminent medical research laboratories in Melbourne, Australia.

#### 2016 CSL YOUNG FLOREY MEDAL

Professor Mark Kendall from the University of Queensland, Australia, was awarded the 2016 CSL Young Florey Medal for his efforts developing a new vaccine technology known as a “Nanopatch”.

The CSL Young Florey Medal was established by CSL and the Australian Institute of Policy and Science to recognise excellence and encourage ongoing achievement in medical research.



Professor Mark Kendall awarded with the CSL Young Florey Medal at the AAMRI annual dinner held at Parliament House Canberra, Australia.

#### SUPPORT FOR BIOMEDICAL COMMUNITIES 2016/17



#### BREAKDOWN OF TOTAL BIOMEDICAL COMMUNITY CONTRIBUTIONS

- BIOMEDICAL EDUCATION & DEVELOPMENT - 39%
- BIOMEDICAL RESEARCH - 61%



## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### RECOGNISING AND ENCOURAGING COAGULATION RESEARCH

In July 2017, CSL Behring announced the recipients of the Professor Heimburger Awards at the Annual Congress of the International Society on Thrombosis and Haemostasis in Berlin, Germany. In total, five recipients – two from the Netherlands and the US and one from France – each received €20,000 to help advance coagulation research.



In Japan, as part of our commitment to the haemophilia community, CSL Behring, in partnership with the Japanese Society on Thrombosis and Hemostasis (JSTH), has launched a fellowship program supporting promising Japanese researchers in the field of haemostasis. Over a five-year period one recipient per year will be selected to receive a stipend for international study to the value of ¥4 million per year.

### INAUGURAL 2016 CSL CENTENARY FELLOWSHIPS

As part of our Centenary celebrations in 2016, CSL announced the establishment of the CSL Centenary Fellowship program, which will run over the next 10 years. The A\$25 million program awards two, five-year A\$1.25-million fellowships each year to early-to-mid career Australian medical researchers, who are working on world-class discovery or translational research in the areas of rare and serious diseases, immunology and inflammation.

In October 2016, our two inaugural fellowships were awarded to Professor Geoff Faulkner from the Queensland Brain Institute and Associate Professor Steven Lane from the QIMR Berghofer Medical Research Institute.

More information on our program can be found on our website: [www.csl.com.au/centenary/fellowships.htm](http://www.csl.com.au/centenary/fellowships.htm).



Professor Geoff Faulkner and Associate Professor Steven Lane are recipients of CSL's inaugural Centenary Fellowships.

## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### SUPPORTING BIOMEDICAL RESEARCH

In addition to direct collaborations with medical research institutes and universities, CSL's support for biomedical research includes research grants to research institutes, hospitals and patient organisations. Significant support is dedicated to investigator-initiated studies (IIS). These research projects are undertaken by investigators outside CSL's R&D activities. For the investigators, these projects seek to advance scientific knowledge in areas of unmet patient need, while extending our own understanding and potential for CSL's therapies to treat new indications or therapy areas. CSL does not have any role in the conduct of the study and does not claim exclusivity over research outcomes, but does provide support through the provision of product and/or financial grants. In 2016/17, with the support of CSL Behring, there were 51 studies in operation, with CSL contributing US\$7 million towards these studies.

### THE ROLE OF C1-ESTERASE INHIBITOR IN ANTIBODY-MEDIATED REJECTION IN KIDNEY TRANSPLANTATION

Antibody mediated rejection (AMR) represents one major challenge in transplantation medicine, with AMR being a major cause of late kidney transplant failure. The study being conducted by the NYU Langone Medical Center, in New York, explores novel approaches to treat and prevent this complication using C1-esterase inhibitor. CSL Behring is supporting the research with the supply of product, free of charge.

### ADVANCING IMMUNOGLOBULIN THERAPY RESEARCH IN NEUROLOGY

To demonstrate CSL's continued commitment to innovative immunoglobulin research, CSL Behring has created the Interlaken Leadership Awards. The awards program provides monetary grants and/or product supply for investigational use that supports innovative medical research and knowledge about the potential role of immunoglobulin therapy to improve the lives of patients who have disabling neurological/neuromuscular conditions.

In July, at the Peripheral Nerve Society's Annual Meeting in Sitges, Spain, CSL Behring announced the 2017 recipients:

- Dr Maarten Titulaer, a neurologist at Erasmus University Medical Center, Rotterdam, Netherlands, who will study intravenous immunoglobulin treatment for autoimmune epilepsy with neuronal antibodies; and
- Dr Jean-Philippe Camdessanché from Institut NeuroMyoGène, Faculty of Medicine CHU de Saint-Etienne, France, who will study the identification, validation and characterisation of novel autoantigens in chronic inflammatory demyelinating polyneuropathy.



**Advancing new research**  
The Interlaken Leadership Awards

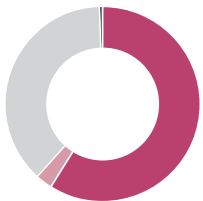
## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### 5.4 SUPPORTING LOCAL COMMUNITIES

#### SUPPORTING EFFORTS WHERE WE LIVE AND WORK

Local community initiatives are centred on engaging employees in local giving, both financially and through volunteered time. These programs invite the broader participation of our employees in the community. While seeking to address a community need or gap, support for the local community encourages teamwork and collaboration and builds a sense of pride in the workplace and organisation. A number of activities are undertaken across our sites to support local organisations.

#### SUPPORT FOR LOCAL COMMUNITIES 2016/17



#### BREAKDOWN OF TOTAL LOCAL COMMUNITY CONTRIBUTIONS

- COMMUNITY DEVELOPMENT – 59%
- DISASTER RELIEF – 2.9%
- EMPLOYEE MATCHING – 37.8%
- SUPPORT FOR THE DISADVANTAGED – 0.3%

#### In Australia:

In March 2017, CSL's givingforgood™ program extended its workplace giving by expanding its payroll giving platform to volunteering. Employees are now better able to utilise their day's paid volunteer leave by searching online for volunteering opportunities with hundreds of charities. The givingforgood program is a partnership with Good Company, a not-for-profit organisation that facilitates monetary donations and the volunteering of time.

At our facility in Broadmeadows, CSL Behring Australia awarded its third A\$20,000 Community Grant to Hume Valley School for their Community Connections program, which offers special-needs students a range of hands-on, alternative education opportunities. The annual grants program was created to help address local needs within or around Broadmeadows, a highly disadvantaged community.



CSL Behring employees in Australia awarded the Hume Valley School a \$20,000 grant to assist with the implementation of their Community Connections program, which seeks to offer young people with mild intellectual disabilities a range of hands-on, alternative education opportunities.



## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### In the US:

Since 2011, CSL Behring's King of Prussia office has donated more than US\$1.3 million to community organisations through its Giving for Good Committee. This total includes US\$281,500 donated to the United Way in 2016/17 through employee contributions and company matching. The committee champions and focuses employee giving, including volunteering, towards a number of organisations, including United Way of Philadelphia and Southern New Jersey, the Ronald McDonald House, and the Young Men and Women in Charge Foundation, Inc.

At CSL Behring in Kankakee, employees and students participating in summer vacation work collaborated for the fourth year to aid local children of low-income families achieve academic success, by raising donations for backpacks filled with school supplies. In addition, the Kankakee United Way employee-giving campaign again garnered the Pinnacle Award, bestowed on the largest local giving campaign. Employees demonstrated their generosity by increasing overall donations from the previous years, with employee and company matching totalling more than US\$153,000. Additionally, employees donated to 14 community organisations, raising more than \$18,000 for local charities.

In Holly Springs, Seqirus dedicated one day in September to allow employees to volunteer with charitable causes in the communities local to the site and to their homes. More than 200 employees spent the day building homes for Habitat for Humanity, preparing meals, painting, landscaping and clerical work for 15 charitable organisations.

Across the US, CSL Plasma centres raised a total of US\$135,881 in the months of April and May 2017 for the Immune Deficiency Foundation (IDF). Both CSL Plasma employees and plasma donors support the fundraising, which contributes towards patient and family education, support services and research and development. In addition, CSL Plasma and employees together donated US\$263,314 to United Way in October 2016. CSL Plasma locations across the country partner with local United Way branches and their affiliated agencies to focus on the building blocks for a good quality of life and a strong local community.



CSL Behring employees in King of Prussia supported Cradles to Crayons, a community organisation that provides children living in homeless or low-income situations with essential items. The organisation's Backpack-A-Thon saw the creation of 30,000 backpacks with school supplies for children.

## 05 SUPPORTING OUR COMMUNITIES CONTINUED

### In Europe:

In Switzerland, CSL Behring continues its recognition of the best and brightest in biomedical sciences at the University of Bern with an award for the three best master's theses. Endowed with a total of 5,000 Swiss Francs, the award encourages young researchers to pursue higher education while promoting the important exchange of ideas between academia and industry. Along similar lines, CSL Behring, in partnership with the Bern Chamber of Commerce and the Canton of Bern, supports a local fair for the advancement of children and young professionals in engineering, technology and the natural sciences.

In addition, as a leader in immunoglobulin research and innovation, CSL Behring is a founding member of the Swiss Institute for Translational and Entrepreneurial Medicine (sitem-insel AG) in Bern. CSL Behring provides expertise in medical technology, engineering and technology transfer. Furthermore, specialists and researchers from CSL's Bern site have been involved in establishing sitem-insel's Swiss School where university-level courses are given by lecturers from industry and

academia designed as continuing professional development for specialists. CSL Behring Bern employees have also been involved in establishing course content and will act as lecturers and teachers at the school.

In Germany, employees support local charitable activities through payroll giving, with Living with Cancer, a local organisation in Marburg, receiving €10,000 in 2017. Furthermore, in December 2016 CSL Behring supported Marburg Food Bank for Children with €2,500. Funds traditionally allocated for the distribution of Christmas cards are now diverted to support local organisations. Like its close neighbour in Switzerland, CSL Behring Marburg employees are also active in encouraging the younger generation to pursue the world of science. In 2016/17, CSL supported numerous programs pitched at exciting interest in the sciences at various levels of education, from encouraging participation in STEM by girls aged 11-14 to holding on-site biochemistry workshops for students from local schools and supporting Marburg University's scholarship program with stipend support for a pharmacy student.

### In Asia:

CSL Behring China continues its support for the annual fundraising campaign Pass-it-On, of the Hong Kong Red Cross. The program encourages the public to support humanitarian work for those in need. CSL Behring has sponsored the campaign for the last decade, demonstrating our commitment to the local community and the work of the Red Cross.

In Japan, CSL Behring participated in the charitable, weekend-long Tohoku Food Marathon & Festival aimed at supporting the recovery and restoration of the regions devastated by the 2011 Tohoku earthquake and tsunami. Employees participated in the run, helping to raise funds for the campaign.

# ASSURANCE STATEMENT



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## Independent Limited Assurance Statement in relation to CSL Limited's ('CSL') 2017 Corporate Responsibility Report

### Our Conclusion:

Ernst & Young ("EY", "we") were engaged by CSL to undertake limited assurance as defined by Australian Audit Standards, here after referred to as a 'review', over a number of selected disclosures included in CSL's Corporate Responsibility Report ('the Report') for the year ended 30 June 2017. Based on our review, nothing came to our attention that caused us to believe that the selected disclosures, have not been prepared and presented fairly, in all material respects, in accordance with the criteria defined below.

### What our review covered:

EY reviewed the selected disclosures, listed below, as disclosed in the Report, for the year ended 30 June 2017.

Selected Disclosures		Page reference:
Our People	Lost Time Injury Frequency Rate (LTIFR)	16, 51
	Medical Treatment Injury Frequency Rate (MTIFR)	
	Days Lost Frequency Rate (DLFR)	
Safety and Quality	Regulatory Audits	28, 51
	Quality audits of suppliers	
	Safety Recalls of finished product	
Economic Contribution	Economic value generated / Economic value distributed	33, 51

### Criteria applied by CSL

In preparing the selected disclosures, CSL applied the:

- ▶ specific criteria from Global Reporting Initiative Sustainability Reporting Guidelines' ('GRI G4')
- ▶ CSL's publicly disclosed criteria as detailed in footnotes in the Report

### Key responsibilities

#### EY's responsibility and independence

Our responsibility was to express a limited assurance conclusion on the selected disclosures included in CSL's 2017 Corporate Responsibility Report.

We were also responsible for maintaining our independence and confirm that we have met the requirements of the APES 110 Code of Ethics for Professional Accountants including independence and have the required competencies and experience to conduct this assurance engagement.

#### CSL's Responsibility

CSL's management was responsible for selecting the Criteria, and fairly presenting the selected disclosures in accordance with that Criteria. This responsibility includes establishing and maintaining internal controls, adequate records and making estimates that are reasonable in the circumstances.

### Our approach to conducting the review

We conducted this review in accordance with the *Australian Standard on Assurance Engagements Other than Audits or Reviews of Historical Financial Information* ('ASAE 3000') and the terms of reference for this engagement as agreed with CSL on 22 May 2017.

### Summary of review procedures performed

A review consists of making enquiries, primarily of persons responsible for preparing the selected disclosures and related information, and applying analytical and other review procedures:

- ▶ Conducting interviews with key personnel at corporate and selected sites to understand CSL's process for collecting, collating and reporting the selected disclosures during the reporting period
- ▶ Checking that the Criteria has been reasonably applied in the calculation and aggregation of the selected disclosures
- ▶ Undertaking data analytics to check the reasonableness of the data supporting disclosures
- ▶ Conducting detailed testing of underlying source information on a sample basis to check completeness and accuracy of data
- ▶ Checking regulatory body websites to confirm accuracy of safety related recall reporting
- ▶ Obtaining audit closure reports to confirm existence of quality audits of suppliers and regulatory audits
- ▶ Comparing classification of safety incidents against the CSL Standard Operating Procedure to confirm accuracy and consistency across the business
- ▶ Inquiring of site personnel to identify risks of underreporting and quality controls in place to address these risks
- ▶ Performing recalculations of performance metrics to confirm quantities stated were replicable
- ▶ Checking aggregation of site-based selected disclosures and transcription to the Report
- ▶ Checking the appropriateness of the presentation relating to the selected disclosures.

We believe that the evidence obtained is sufficient and appropriate to provide a basis for our limited assurance conclusion.

### Limited Assurance

Procedures performed in a limited assurance engagement vary in nature and timing from, and are less in extent than for, a reasonable assurance engagement. Consequently, the level of assurance obtained in a limited assurance engagement is substantially lower than the assurance that would have been obtained had a reasonable assurance engagement been performed.

While we considered the effectiveness of management's internal controls when determining the nature and extent of our procedures, our assurance engagement was not designed to provide assurance on internal controls. Our procedures did not include testing controls or performing procedures relating to checking aggregation or calculation of data within IT systems.

### Use of our Assurance Statement

We disclaim any assumption of responsibility for any reliance on this assurance report, or on the Subject Matter to which it relates, to any persons other than management and the Directors of CSL, or for any purpose other than that for which it was prepared.

Our review included web-based information that was available via web links as of the date of this statement. We provide no assurance over changes to the content of this web-based information after the date of this assurance statement.

Ernst & Young  
 Melbourne, Australia  
 25 October 2017

Terence Jeyaretnam FIEAust  
 Partner

## KEY PERFORMANCE DATA SUMMARY#

ECONOMIC CONTRIBUTION		2014/15	2015/16	2016/17	
Economic value generated	US\$million	5,628	6,129	6,934	For more see page 33.
Economic value distributed	US\$million	5,009	6,098	6,909	
INNOVATION		2014/15	2015/16	2016/17	
R&D investment	US\$million	463	614	645	For more see page 20.
SAFETY AND QUALITY		2014/15	2015/16	2016/17	
Regulatory audits	Number	263	273	343	For more see page 28.
Quality audits of suppliers	Number	497	574	609	
Safety related recalls of finished product	Number	3	3	4	
OUR PEOPLE		2014/15	2015/16	2016/17	
Total headcount	Number	14,874	17,021	19,637	For more see pages 16 and 18.
Lost time injury frequency rate (LTIFR)	Per million hours worked	0.75	1.04	1.56	
Medical treatment injury frequency rate (MTIFR)	Per million hours worked	6.22	4.98	4.13	
Days lost frequency rate (DLFR)	Per million hours worked	17.82	15.69	33.27	
Fatalities (including contractors)	Number	0	0	0	
COMMUNITY		2014/15	2015/16*	2016/17*	
Total contribution	US\$million	28.4	29.6	40.0	For more see page 41.
ENVIRONMENT		2014/15	2015/16	2016/17	
Energy consumption	Petajoules	2.43	2.87	3.17	More on our website: <a href="http://corporateresponsibility.csl.com.au">http://corporateresponsibility.csl.com.au</a> .
Greenhouse gas emissions	Metric kilotonnes	240	303	334	
Water consumption	Gigalitres	2.69	3.14	3.43	
Waste	Metric kilotonnes	21.83	44.07	33.07	
Waste recycling rate	%	59	52	51	

# 2014/15 data does not include data from the acquired Novartis influenza vaccine business.

\* 2015/16 does not include data from the acquired Novartis influenza vaccine business. 2016/17 includes some data from the acquired Novartis influenza vaccine business.

## MEDICAL GLOSSARY

**Acute Myocardial Infarction** is a heart attack.

**Adjuvant** is a substance which enhances the body's immune response to an antigen.

**Albumin** is any protein that is soluble in water and moderately concentrated salt solutions and is coagulable by heat. It is found in egg whites, blood, lymph, and other tissues and fluids. In the human body serum albumin is the major plasma protein (approximately 60% of the total).

**Alpha-1 Antitrypsin Deficiency (AATD)** is an inherited condition that causes low levels of, or no, alpha-1 antitrypsin (AAT) in the blood. AATD is a protein made in the liver and enables normal function of the lungs.

**Anti-D immunoglobulin**, also called Rh(D) immunoglobulin, is an injection of anti-rhesus antibodies given to a woman whose blood group is rhesus negative, if there is a chance that she has been exposed to rhesus positive blood either during pregnancy or blood transfusion.

**Autoimmune Disease** is when the body's immune system attacks healthy cells.

**Biopharmaceuticals** are proteins (including antibodies), nucleic acids (DNA, RNA or antisense oligonucleotides) used for prophylactic or therapeutic purposes.

**Cell-Based (Technology)** is a process of growing viruses in animal cells.

**C1 Esterase Inhibitor** is a protein found in the fluid part of blood that controls C1, the first component of the complement system. The complement system is a group of proteins that move freely through the blood stream. These proteins work with the immune system and play a role in the development of inflammation.

**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** is a neurological disorder which causes gradual weakness and a loss in sensation mainly in the arms and legs.

**Coagulation** is the process of clot formation.

**Common Variable Immune Deficiency** is one of the most frequently diagnosed primary immunodeficiencies, especially in adults, characterised by low levels of immunoglobulins and antibodies, which causes an increased susceptibility to infection.

**Diabetes, Type 2** is a chronic condition that occurs when the pancreas does not produce enough insulin and/or the insulin does not work effectively.

**Fibrinogen** is a coagulation factor found in human plasma that is crucial for blood clot formation.

**Fractionation** is the process of separating plasma into its component parts, such as clotting factors, albumin and immunoglobulin, and purifying them.

**G-CSF** is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream.

**Haemolytic Disease** is a disease that disrupts the integrity of red blood cells causing the release of haemoglobin.

**Haemophilia** is a haemorrhagic cluster of diseases occurring in two main forms:

1. Haemophilia A (classic haemophilia, factor VIII deficiency), an X linked disorder due to deficiency of coagulation factor VIII.
2. Haemophilia B (factor IX deficiency, Christmas disease), also X linked, due to deficiency of coagulation factor IX.

**Haemostasis (Haemostatic)** is the stopping of blood flow.

**Haemolysis** is the rupture and destruction of blood cells.

**Hereditary Angioedema (HAE)** is a rare but serious genetic disorder caused by low levels or improper function of a protein called C1 esterase inhibitor. It causes swelling, particularly of the face and airways, and abdominal cramping.

**Hereditary Emphysema** is a physiological condition that results in excessive amounts of white blood cells (neutrophils) to enter the lungs and cause inflammation and chronic lung disease.

**Human Papilloma Virus (HPV)** is a diverse group of DNA-based viruses that infect the skin and mucous membranes of humans and a variety of animals. Some HPV types cause benign skin warts, or papillomas, for which the virus family is named. Others can lead to the development of cervical dyskaryosis, which may in turn lead to cancer of the cervix.

**Immunoglobulins (Ig)**, also known as antibodies, are proteins produced by plasma cells. They are designed to control the body's immune response by binding to substances in the body that are recognised as foreign antigens (often proteins on the surface of bacteria or viruses).

**Influenza**, commonly known as flu, is an infectious disease of birds and mammals caused by a RNA virus of the family Orthomyxoviridae (the influenza viruses).

**Intravenous** is the administration of drugs or fluids directly into a vein.

**Isoagglutinins** are antibodies produced by an individual that cause agglutination of red blood cells in other individuals

**Leukaemia** is a group of cancers that affect the blood and bone marrow.

**Monoclonal Antibody (mAb)** is an antibody produced by a single clone of cells. Monoclonal antibodies are a cornerstone of immunology and are increasingly coming into use as therapeutic agents.

**Neurological** is the science of nerves and the nervous system.

**Neutrophil Infiltration** is the diffusion or accumulation of neutrophils (white blood cells) in tissues or cells in response to a wide variety of substances released at the sites of inflammatory reactions.

**Perioperative Bleeding** is bleeding during an operation.

**Plasma** is the yellow-coloured liquid component of blood in which blood cells are suspended.

**Primary Immunodeficiency (PID)** is an inherited condition where there is an impaired immune response. It may be in one or more aspects of the immune system.

**Prophylaxis** is the action of a vaccine or drug that acts to defend against or prevent a disease.

**Quadrivalent Influenza Vaccine** is a vaccine that offers protection against four different influenza virus strains.

**Recombinants** are proteins prepared by recombinant technology. Procedures are used to join together segments in a cell-free system (an environment outside a cell organism).

**Secondary Immunodeficiency Disease** occurs when the immune system is compromised due to an external factor (i.e. not genetic).

**Subcutaneous** is the administration of drugs or fluids into the subcutaneous tissue, which is located just below the skin.

**Thrombosis** is the formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system.

**Trivalent Influenza Vaccine** is a vaccine that offers protection against three different influenza virus strains.

**Von Willebrand Disease (vWD)** is a hereditary disorder caused by defective or deficient von Willebrand factor, a protein involved in normal blood clotting.

**Warfarin** is an anticoagulant used to prevent heart attacks, strokes, and blood clots.

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