



Sustainability Report 2016

maynepharma.com



You deserve tomorrow.



About this report

This is the first Sustainability Report (the report) published by Mayne Pharma Group Limited (Mayne Pharma or the Company) and has been prepared in accordance with the Global Reporting Initiative (GRI) Standards. The report spans the period from 1 January 2016 until 31 December 2016 and covers the economic, environmental and social impacts of Mayne Pharma's operations globally. The report includes information pertaining to Mayne Pharma and its 100% controlled entities (the Group) during the reporting period.

Mayne Pharma has prepared this report in consultation with ACCSR, in accordance with the GRI 'core reporting' requirements. The report has not been externally assured.

We welcome feedback on our Sustainability Report. For any feedback, please contact Lisa Pendlebury, VP Investor Relations & Communications on +61 3 8614 7706 or lisa.pendlebury@maynepharma.com.

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Our People



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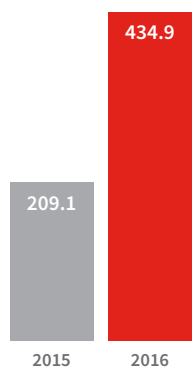
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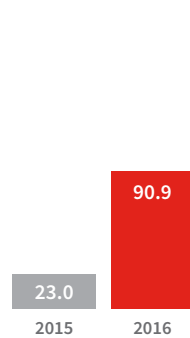
Performance Highlights

Financial (Calendar year)

Revenue (AUD\$m)



Net Profit after tax (AUD\$m)



Global tax paid (AUD\$m)



R&D investment (AUD\$m)



Products

US product portfolio

2016



59

Marketed products
(2015: 21 Marketed products)

People

763

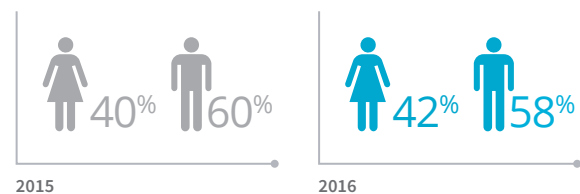
Employees across
Australia and the US

706 51 6
Full time Part time Casual

Lost Time Injury frequency rate (LTIs per million hours worked)

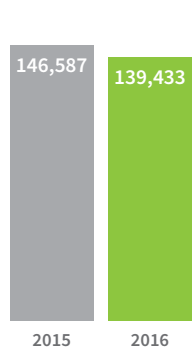


Gender diversity (number)

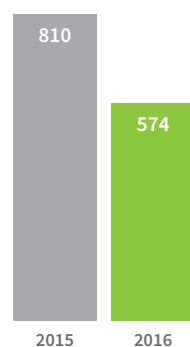


Environment

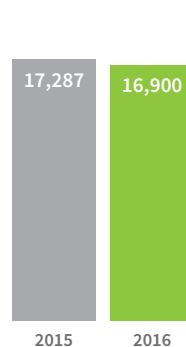
Total Scope 1&2 energy consumption (GJ)



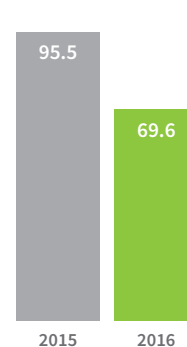
Total energy intensity (GJ / AUD\$m of revenue)



Total GHG emissions (tCO₂e)



Total GHG intensity (tCO₂e / AUD\$m of revenue)



Chairman and Managing Director's Report

We are proud to share with you Mayne Pharma's first Sustainability Report which outlines the key economic, social and environmental impacts arising from Mayne Pharma's activities, and the ways in which Mayne Pharma monitors and responds to these.



Scott Richards, CEO



Roger Corbett, Chairman

At Mayne Pharma, we recognise that we are part of a global community. As part of this community, we are committed to operating our business in a sustainable manner that ensures our people are safe and well-supported, local communities prosper and the environment is well cared for so that it benefits future generations.

The pharmaceutical industry is responsible for improving living standards around the world and enabling people to live longer and healthier lives. Mayne Pharma's key focus is to bring better and more affordable medicines to market enabling patients to better manage diseases and their health.

Our responsibilities as an organisation are to the patients and consumers we serve, our employees, the communities in which we operate and our shareholders. We endeavour to attract and retain the best talent, promote a safe and healthy work environment, deal ethically and fairly with all stakeholders, prevent or minimise any environmental impact, encourage innovation in product design and deliver superior returns to our shareholders.

Releasing our first Sustainability Report is an important milestone for Mayne Pharma and reflects the increasing scale, reach and impact of Mayne Pharma along with the growing demand from stakeholders for this type of information. We are proud of our achievements and developments in this area, and we are delighted to outline them for you in this report. We have committed to report in line with the Global Reporting Initiative Standards, the leading framework for sustainability reporting, which demonstrates our commitment to adopt best practice in this important area.

The 2016 calendar year was a successful and productive one for Mayne Pharma on the back of strong operational performance across the Group. Mayne Pharma achieved revenue of A\$435million and annual net profit after tax of A\$91million. New product launches, product acquisitions and increased

penetration of key product franchises contributed to the strong financial result.

In the US, our most important market, the Company significantly expanded its product portfolio and now markets 59 products (up from 21 in 2015). During the year, the Company received two significant US FDA product approvals - dofetilide capsules, the first generic alternative to Pfizer's Tikosyn® brand and Doryx® MPC, a new product in the Doryx® family. These products have provided new treatment options and more choices in terms of medication affordability for patients.

The Company continues to commit significant resources to research and development with A\$30 million invested over the year. Most of this investment was directed towards the development of generics currently available from few sources, which are expected to provide further choices to patients in terms of medication affordability.

As we reflect on our achievements over 2016, we can look to the future with confidence. Mayne Pharma is not only committed to delivering strong financial performance but also being an employer that offers a rewarding and safe work environment whilst working in a sustainable ethical way with our communities.

We would like to take this opportunity to sincerely thank all of the dedicated staff and contractors who have helped us to reach our goals and deliver on our commitments. Without your hard work none of this would be possible.

Roger Corbett, AO
Chairman

Scott Richards,
Managing Director

Our Approach



Our People



Our Products



Our Operations



Our Contribution



GRI Index





The Mayne Pharma Story

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on the application of drug delivery expertise to commercialise branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Business Overview

Mayne Pharma's roots can be traced back to FH Faulding and Co Limited, for many years, one of the largest and most prominent public companies headquartered in South Australia.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world including Doryx®, Kapanol®, Eryc®, Astrix® and Lozanoc®.

To accelerate the commercialisation of the Company's pipeline of products under development, the business invested approximately A\$30m in research and development in 2016. This investment in R&D has grown five-fold since 2012.

Mayne Pharma has two product development and manufacturing facilities, one based in Salisbury, South Australia, Australia and the other in Greenville, North Carolina, US with expertise in the formulation of complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds.

In late 2015, Mayne Pharma announced the construction of a new 11,600 square metre (125,000 square foot) solid oral dose manufacturing facility in Greenville, with construction commencing during 2016. The investment will more than double the current US operational footprint to 20,900 square metres (225,000 square feet) and create new capacity and

Mayne Pharma is a specialty pharma business with diversified operations across the value chain



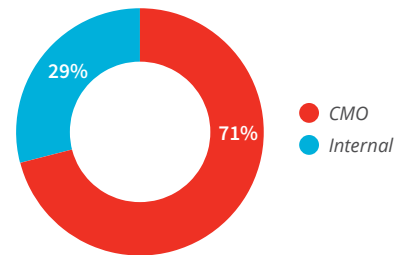
capability to accelerate growth. In Australia, Mayne Pharma announced additional strategic investments at the Company's manufacturing facility in Salisbury to expand fluid bed processing capacity and add new potent handling capability.

Mayne Pharma currently markets more than 70 products globally and has a pipeline of more than 50 products under development. In 2016, 92% of the Company's revenue was generated in the US, with Australia representing 6% of revenue. Mayne Pharma also sells its products through distribution partners in numerous other countries, including Canada, Korea, UK, Thailand, Spain and Switzerland, which accounted for 2% of revenue in 2016.

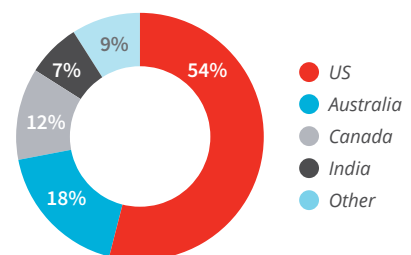
Mayne Pharma has over 2,000 suppliers that provide the materials, goods and services required to conduct research and development, manufacture products, service our customers and supply our operations and facilities around the world. Our suppliers include 16 contract manufacturing organisations (CMOs) and partners and over 40 active pharmaceutical ingredient suppliers.

Mayne Pharma's workforce comprises over 750 people of which 70% are based in the US and the remainder in Australia.

Product manufacture
(by product)



Country of finished goods manufacture
(by product)



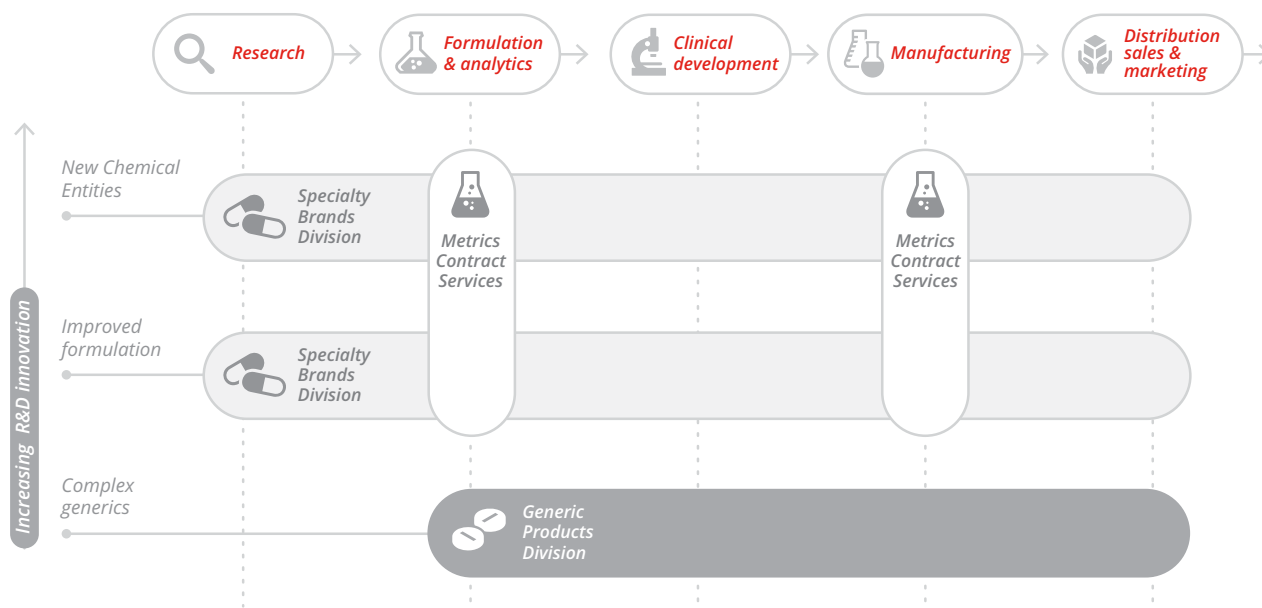
Mayne Pharma's business units and services are:

	US BUSINESS UNITS			REST OF WORLD
Description	Generic Products <i>Develops, manufactures, markets and distributes generic products in the US</i>	Specialty Brands <i>Markets, manufactures and distributes specialty branded products in the US</i>	Contract Services <i>Provides contract pharmaceutical development and analytical services to third party customers globally</i>	Mayne Pharma International <i>Develops, manufactures, markets and distributes branded and generic products globally (excl. US)</i>
Strategy	<ul style="list-style-type: none"> Focus on hard to develop and manufacture products Optimise market penetration of product portfolio Rapidly commercialise new approved products 	<ul style="list-style-type: none"> Develop and market clinically differentiated products with therapeutic value in dermatology Build new specialty therapeutic platforms 	<ul style="list-style-type: none"> Provide contract services in niche and scientifically challenging areas Globalise customer base Deliver high quality and reliable contract manufacturing 	<ul style="list-style-type: none"> Commercialise growing Australian product portfolio Build specialty brands and injectable franchise in Australia Out-licence Lozanoc® and Kapanol® in new markets
Key products & services	<ul style="list-style-type: none"> Butalbital / APAP / Caffeine Carbidopa / Levodopa Clonidine Dextroamphetamine Dofetilide Liothyronine Methamphetamine Methylphenidate Oxycodone Range of oral contraceptives 	<ul style="list-style-type: none"> Doryx® Doryx® MPC Fabior® Sorilux® 	<ul style="list-style-type: none"> Analytical services (method development and validation, drug substance and drug product release, stability, and trace metals analysis) Formulation development (incl. clinical trials manufacturing) 	<ul style="list-style-type: none"> Astrix® Doryx® Eryc® Lozanoc® / Itragerm® Kapanol® / Kadian® Luxiq® Magnoplasma® Olux-E® Range of injectable products



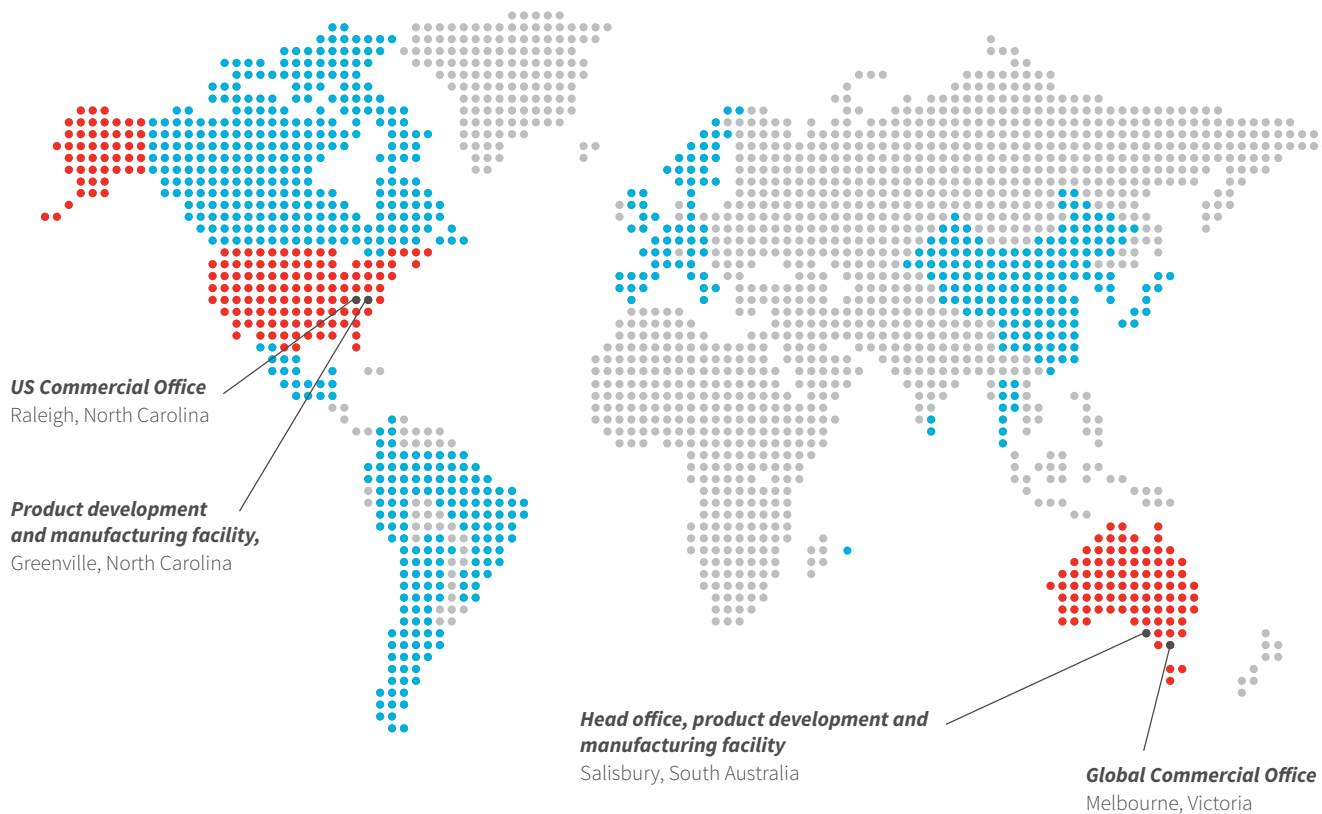
Our Approach

Participation of Mayne Pharma across the pharmaceutical value chain



Our global presence

● Direct commercial presence ● Indirect presence through distribution partners for current and pipeline products



Our Values

Mayne Pharma is committed to providing an environment that allows people to feel respected, appreciated and included. By living Our Values, Mayne Pharma provides a framework to guide how we treat each other, our customers and our partners.

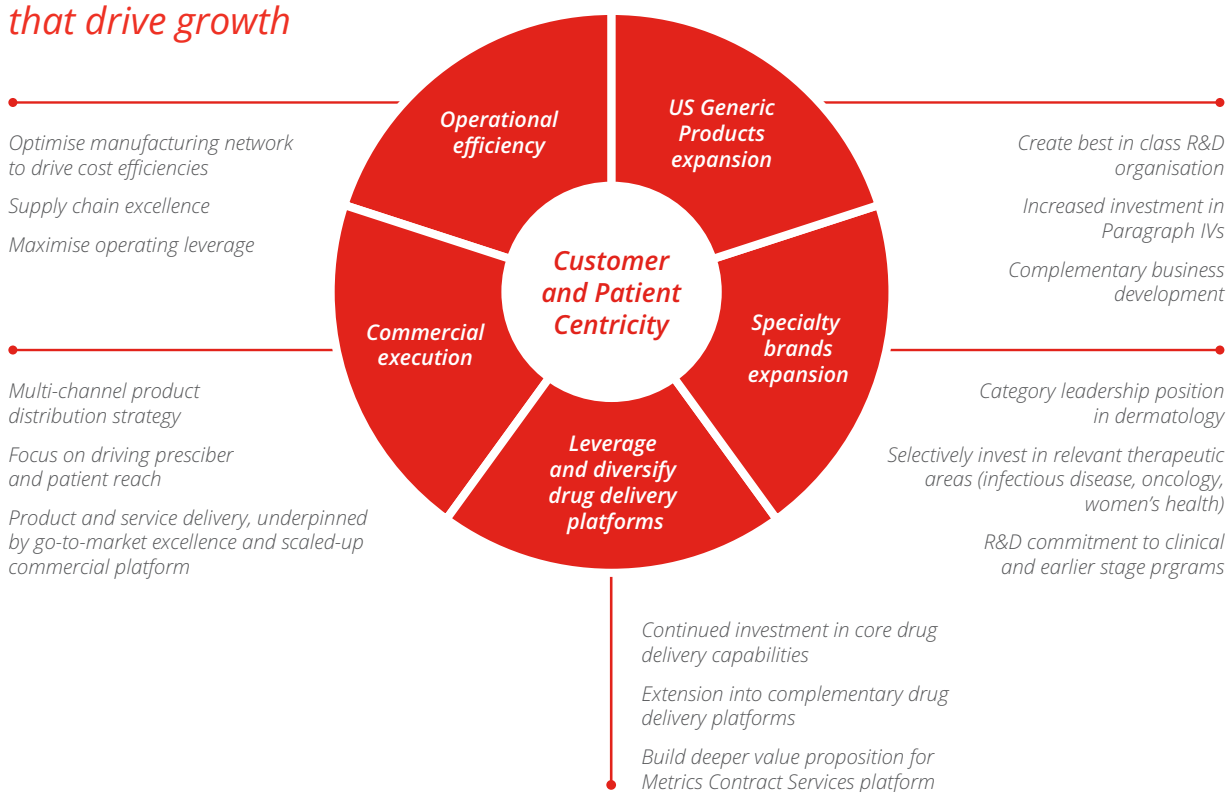
The Company has grown substantially over the last four years and this growth reflects the hard work and dedication of our employees. Our Values help our people to feel connected to the organisation, understand how they fit in to the global organisation and assist to create a workplace that is conducive to initiatives and activities that are challenging and rewarding. Our Values are:

- **Integrity** – maintaining high ethical standards, demonstrating honesty, and respecting fairness by doing the right thing, even when no one is looking.
- **Empowerment** – encouraging everyone to take initiative, enabling growth and achievement.
- **Passion** – showing pride, enthusiasm and dedication in everything we do.
- **Creativity** – delivering value and striving to connect new ideas with business realities.
- **Agility** – operating with timeliness as well as mental, emotional and physical flexibility.
- **Accountability** – accepting our individual and team responsibilities, meeting our commitments, and acknowledging and learning from mistakes.

Mayne Pharma's Vision

"At Mayne Pharma we are focused on delivering a healthier tomorrow. We believe that everyone deserves medicines that are better, safer and more affordable. That's why our people are determined to create clever, innovative products and services for our changing world."

Five strategic pillars that drive growth





Sustainability at Mayne Pharma

We believe our business is strengthened by engaging and fostering relationships with our key internal and external stakeholders in social, environmental and governance matters



Our key sustainability objectives are:

- *Attract and retain the best talent*
- *Promote a safe and healthy work environment across our businesses*
- *Deal ethically, fairly and equitably with all stakeholders*
- *Prevent or minimise any impact on the environment by promoting efficient use of natural resources and minimising emissions and waste*
- *Encourage innovation in product design to minimise impact on the environment*
- *Meet or exceed our statutory obligations and commitments*
- *Deliver superior returns to shareholders*

Mayne Pharma's first sustainability report endeavours to outline our sustainability approach, performance for the past year and commitments for the coming year. Being our first report, we have provided limited comparative data. We recognise the need to further strengthen our measurement systems for certain sustainability indicators and are currently establishing systems to capture a wider set of metrics. Case studies have been used to further illustrate our sustainability approach where appropriate. We welcome dialogue on our performance and invite investors, analysts and other stakeholders to engage with us directly.

Our Stakeholders

Mayne Pharma recognises the importance of stakeholder engagement. We believe our business is strengthened by engaging and fostering relationships with our key internal and external stakeholders in social, environmental and governance matters. Our key stakeholders include suppliers who contribute to the manufacture of our products; the customers who purchase our products; the doctors, nurses and patients who use our products; our employees; local communities; regulatory authorities and investors. Mayne Pharma regularly engages with its stakeholders through a variety of mechanisms to ensure the Company meets their needs. Stakeholder engagement mechanisms and examples of key interests identified, are outlined below:

STAKEHOLDER GROUP	ENGAGEMENT MECHANISM	EXAMPLES OF KEY INTERESTS
Customers	<ul style="list-style-type: none"> Meetings Customer visits / audits 	<ul style="list-style-type: none"> Quality of products Reliability of supply Product pricing
Employees	<ul style="list-style-type: none"> Half yearly performance reviews Management committees Employee engagement surveys Intranet / newsletters Site meetings Community and wellness committees 	<ul style="list-style-type: none"> Workplace health and safety Career development
Government / regulators	<ul style="list-style-type: none"> Meetings Reports Site visits Submissions 	<ul style="list-style-type: none"> Efficacy / safety of drugs Compliance
Health professionals	<ul style="list-style-type: none"> Meetings Education seminars 	<ul style="list-style-type: none"> Efficacy / safety of products
Investment community	<ul style="list-style-type: none"> ASX announcements Corporate website Investor briefings and forums 	<ul style="list-style-type: none"> Economic performance Governance Research and development
Local communities	<ul style="list-style-type: none"> Industry bodies Educational Institutions Charities Staff engagement in local events 	<ul style="list-style-type: none"> Community impacts Education and healthcare Advanced education Teaching assistance
Patients	<ul style="list-style-type: none"> Product packaging and labelling Customer call centres Websites Clinical trials Market research Patient savings programs 	<ul style="list-style-type: none"> Product safety Pricing Product access
Shareholders	<ul style="list-style-type: none"> Financial results reporting Annual General Meeting ASX announcements Corporate website Investor roadshows, briefings and forums 	<ul style="list-style-type: none"> Economic performance
Suppliers	<ul style="list-style-type: none"> Site visits / audits Meetings 	<ul style="list-style-type: none"> Business ethics Compliance Quality / reliability





Our Approach

Our Material Issues

Mayne Pharma conducted its first materiality review with assistance from the Australian Centre for Corporate Social Responsibility (ACCSR) which undertook an independent analysis to help identify the issues most material to Mayne Pharma for sustainability reporting and strategy development. Through this process, seven issues were identified as most important to our business and stakeholders and our most significant sustainability impacts. This report details the company's performance in, and activities undertaken to, support these material issues.

MATERIAL ISSUE	VALUE CHAIN BOUNDARY	REFERENCE IN THIS REPORT
Employee health and safety Ensuring our employees work in a safe environment, which meets or exceeds relevant regulatory expectations, addresses health and safety concerns as they arise and mitigates opportunities for reoccurrence of incidents.	Inside the organisation	<ul style="list-style-type: none"> • Our Values (Page 9) • Our People (Page 18) • Ethical Sourcing (Page 27)
Product pricing and accessibility Strategies and initiatives designed to provide more affordable pharmaceutical pricing and accessibility to products for patients through development, manufacture and marketing of high quality generic and branded products.	Inside and outside the organisation	<ul style="list-style-type: none"> • Our Products (Page 24) • Our Socio-Economic Contribution (Page 32)
Product quality and safety to customers Choosing materials from quality sources, complying with current Good Manufacturing Practice, and delivering fit-for-purpose, safe products to customers. Mayne Pharma aims to adhere to, or exceed strict regulatory standards in all jurisdictions that it serves, and investigates all concerns to ensure our products maintain the highest quality.	Inside and outside the organisation	<ul style="list-style-type: none"> • Product quality and safety (Page 26)
Corruption and bribery Business must be conducted with transparency, and free from unethical persuasion. Ethical business practices relate to every aspect of Mayne Pharma's business, from identifying product sources, through development of pharmaceuticals, transactions with regulatory bodies and sale to customers.	Outside the organisation	<ul style="list-style-type: none"> • Anti-Corruption and Anti-Bribery (Page 17) • Code of Conduct (Page 16)
Ethical purchasing and human rights in the supply chain Responsibility to partners to ensure our product line is free from human rights concerns such as forced labour and trafficking, unsafe labour standards and unfair treatment. These issues can arise in all areas of the organisation where human resources are utilised across the supply chain.	Outside the organisation	<ul style="list-style-type: none"> • Ethical Sourcing (Page 27) • Code of Conduct (Page 16)
Compliance Responsibility to drive compliance with legal and regulatory requirements applicable to our global business. Includes training programs, continuous improvement and striving for best-practice. Consequently, compliance affects every aspect of what we do, to deliver quality products to consumers.	Inside the organisation	<ul style="list-style-type: none"> • Governance, Compliance and Risk Management (Page 14)
Resource use and waste management Includes energy usage during manufacture and logistics, water usage and waste as a by-product of manufacture. Stakeholders increasingly demand disclosure of resource usage and waste management for a more sustainable product investment.	Inside the organisation	<ul style="list-style-type: none"> • Our Operations (Page 28)



Our Approach



Our People



Our Products



Our Operations



Our Contribution



GRI Index





Governance, Compliance and Risk Management

Mayne Pharma is committed to the highest standards of corporate governance and transparency and regularly reviews its governance practices, taking into account the recommendations in the Corporate Governance Principles and Recommendations published by the Australian Securities Exchange Corporate Governance Council.

We have a suite of policies that govern our business activities and articulate our expectations for ethical business behaviours. These include:

- Business Code of Conduct
- Anti-bribery policy
- Diversity policy
- Compliance policy
- Misconduct and whistle blowing policy
- Environment, health and safety policy
- Securities trading policy
- Communications policy
- Continuous disclosure policy
- Risk management framework
- Quality policy

Governance framework

The Board of Mayne Pharma is responsible for overseeing and guiding the management of the Group with the aim of protecting and enhancing the interests of its shareholders and considering the interests of other stakeholders including employees and the wider community. The Board is also responsible for identifying significant business risks and ensuring arrangements are in place to adequately manage those risks.

The Chief Executive Officer who is also an Executive Director has operational responsibility for sustainability risks. Management assist with the formulation and implementation of sustainability policies across the organisation. The Board monitors sustainability as it relates to health, safety, the environment and our people. The Corporate Executive Committee (CEC)

is responsible for operational decision making on economic, environmental and social impacts.

Compliance

In 2016, we introduced several new policies to build on the concepts contained in our Business Code of Conduct, including standalone policies related to compliance and whistleblowers. We continued to strengthen our culture of compliance across the organisation through more structured training programs for staff, aiming for a consistent global approach to compliance.

In 2016, Mayne Pharma reviewed and updated its Business Code of Conduct. All Mayne Pharma staff globally participated in face to face training on the updated Business Code of Conduct as well as specific compliance policies covering issues such as responsible business activities, whistleblowing and securities trading.

Mayne Pharma disclosed ongoing litigation in the [FY16 Annual Report](#) under contingencies on page 75. This covers patent litigation and anti-trust matters.

During the period, Mayne Pharma disclosed that it was one of several generic companies to receive a subpoena from the Antitrust Division of the US Department of Justice seeking information relating to the marketing, pricing and sale of select generic products. The investigation relating to Mayne Pharma is focused on doxycycline hyclate delayed-release tablets and potassium chloride powder. Multiple US states have commenced legal proceedings in the United States District Court of Connecticut against a number of US generic companies including Mayne Pharma. Select US states allege that Mayne Pharma engaged in conduct in the doxycycline hyclate delayed-release market that was anti-competitive. Civil actions have also been filed by purchasers. Mayne Pharma continues to cooperate with the DOJ in its investigation.

Governance structure



Our Approach



Our People



Our Products



Our Operations



Our Contribution



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Our Approach

Risk Management

The Board accepts that taking and managing risk is central to building shareholder value and the Board is responsible for the Group's risk management strategy. Management is responsible for implementing the Board's strategy and for developing policies and procedures to assist the Board to identify, manage and mitigate the risks across the Group's operations.

The Company employs executives and retains consultants each with the requisite experience and qualifications to enable the Board to manage the risks to the Company. The Board has requested the Audit & Risk Committee oversee the Group's risk management processes and procedures.

The Group's identification and management of business risks is set out in a Risk Management Framework. The Framework is based on AS/NZS ISO 31000:2009 and provides a framework under which we can categorise the risks that are faced by the Group; the likelihood, consequence and potential impact if the risk were to eventuate, and the residual risk faced by the Group given the existence of appropriate controls.

The risks faced by the Company are diverse and vary significantly in terms of the likelihood of the event occurring and the consequence of such an event. Each specific risk is identified and risk register allocated to a member of the CEC and managed through day-to-day operations and compliance with appropriate, tailored standards and controls.

The risk register is updated by the CEC and reviewed by the Audit and Risk Committee. The Audit and Risk Committee most recently reviewed the risk register at its February 2017 meeting. A summary of the [Risk Management Framework](#) is disclosed on the Company's website.

In December 2016, the Company appointed a Global Vice President of Governance, Risk and Compliance who works closely with the Audit and Risk Committee and the CEC to strengthen our Risk Management Framework and processes.

Code of Conduct

Mayne Pharma strives to provide a dynamic, rewarding and safe place to work and is committed to acting consistently with the highest ethical standards and in strict compliance with the law in all its operations. To achieve this there are important standards and rules that all Directors, executives and other employees must be aware of and follow, that ensure all actions and decisions support our values, vision and objectives. The Company's [Business Code of Conduct](#) covers a broad range of matters and refers to those practices necessary to maintain confidence in the Company's integrity, including procedures in relation to:

- compliance with the law;
- business and financial records;
- workplace health and safety;
- conduct within and outside the workplace;
- confidentiality and use of information;
- conflict of interest;
- equal opportunity;
- whistleblowing;
- anti-trust / dealings with third parties;
- data protection and privacy; and
- bribery and corruption.

The Code of Conduct applies to Directors, executives and other employees, and directs individuals to report any contraventions of the Code of Conduct to their superior or the Chief Executive Officer. We also expect contractors, vendors and any other parties directly representing Mayne Pharma to comply with our Code of Conduct.

Whistleblower Protection Policy

Mayne Pharma has adopted a Misconduct and Whistleblower policy that provides a framework for staff and others to raise concerns about misconduct or activities that don't comply with our policies, and provides detail on our commitment to treat people with respect when they speak out if faced with an integrity or other ethical concern. Employees are encouraged to make reports as early as possible, and can raise matters of concern with their supervisors, our human resources, compliance or legal teams or by making an anonymous report to an independent third party.

Mayne Pharma strives to provide a dynamic, rewarding and safe place to work and is committed to acting consistently with the highest ethical standards and in strict compliance with the law in all its operations

Anti-Corruption and Anti-Bribery

The Company's Business Code of Conduct outlines Mayne Pharma's zero tolerance policy towards bribery and corruption. The Company has a robust training program to give our employees the awareness and knowledge to comply with applicable laws and regulations and to reinforce that the Company will not tolerate any act of impropriety. Our activities must comply not only with company policies but with applicable laws in all countries in which we do business.

Our policy prohibits the offer, promise or giving of any payment or benefit at any time to an individual or entity for the purpose of improperly influencing decisions or actions with respect to our business. This applies to direct engagements (e.g., those driven by our company) as well as to indirect engagements (e.g., those managed through a third-party intermediary or partner).

We conduct Anti-Bribery / Anti-Corruption training with relevant employees who engage with third parties including government officials. We are currently reviewing and enhancing the global Anti-Corruption and Anti-Bribery program with supporting global standard operating procedures.

Our agreements with third party distributors who market and sell our products contain obligations requiring the distributors to comply with all relevant Anti-Bribery / Anti-Corruption laws and regulations.

Anti-Competitive Behaviour

Mayne Pharma's compliance program ensures employees are aware of and have the relevant knowledge to comply with anti-trust laws and regulations (sometimes referred to as competition law). Anti-trust laws differ across different jurisdictions so training and other elements of the program are



tailored as required to ensure that employees are aware of the laws and regulations that affect them.

The Business Code of Conduct outlines general principles to safeguard against violations of anti-trust/competition law. These principles are expanded in training programs provided to those employees who interact with external parties and are therefore at risk of engaging in or witnessing anti-competitive conduct. Training is conducted in small groups on a regular basis, with examples provided to explain how the laws and regulations may affect each person's day-to-day work and when an issue may arise so they are able to respond appropriately.

Mayne Pharma has significantly strengthened its anti-trust compliance program over the last 12 months and continues to enhance its policy and supporting procedures around anti-trust compliance and its pricing function.





Health and Safety

Mayne Pharma is committed to providing a healthy and safe work environment for its employees, contractors and visitors. We promote health, safety and wellbeing in the workplace and constantly strive to equip our people with the right skills to perform their roles. We provide training and development opportunities for staff and encourage a supportive and inclusive culture.

Protection of employee health and safety is a fundamental aspect of Mayne Pharma's employee value proposition and is an operational imperative of the Company by which the behaviours of all employees are measured.

Pharmaceutical manufacture and related activities such as laboratory activities and plant and equipment maintenance carry inherent risks associated with chemicals and machinery that have known employee and environmental health and safety concerns.

Ultimate responsibility for environment, health and safety (EHS) sits with the CEO, supported by leaders and managers who have been delegated authority and accountability for EHS in their areas of responsibility and influence. At Board level, oversight of EHS resides within the Audit & Risk Committee, which has the authority for the establishment and maintenance of a framework of internal control and ethical standards for the management of the Company.

Accountability for the management of EHS is delegated to functional, departmental and team leadership. At the most senior level the company has a Global EHS Steering Committee (GEHSSC) consisting of nominated senior leaders and EHS Functional leads providing a forum for leadership of the global EHS management system. The primary function of the GEHSSC is to ensure the Company demonstrates due diligence in the duties and obligations outlined in EHS legislation and Global EHS Policy.

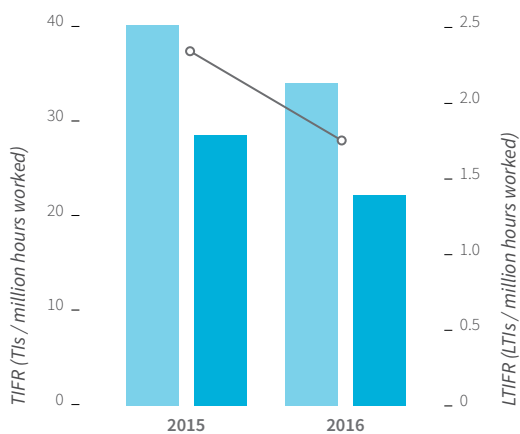
Each country has a functional lead of EHS, residing at the manufacturing sites at Salisbury, South Australia and Greenville, North Carolina. Each region also has dedicated EHS specialists who work in consultation and collaboration with leaders, management and employees to identify, develop, implement, monitor, review and continuously improve the EHS Management Systems in each region.

The regional EHS Management Systems have defined policies, procedures and work practices for the elimination or mitigation of EHS hazards and risks, aligned to regional regulatory requirements and fundamental principles of management systems as defined by region.

In addition to compliance with all applicable EHS regulations throughout our operations, the Company continually strives to create a culture of EHS excellence that impacts the way our employees approach everything they do.

During 2016, we reduced the frequency of work-related injuries at our facilities around the world and number of lost workdays. We investigate all workplace injuries and near-misses, developing and implementing corrective and preventive actions to prevent recurrence.

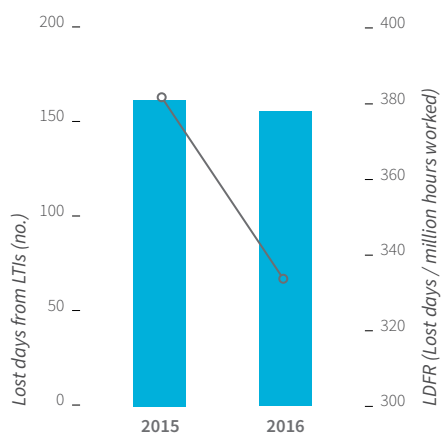
Health and Safety performance - Injuries



● Total Injury Frequency Rate (TIFR) - Australia
 ● TIFR - US
 ○ Lost Time Injury Frequency Rate (LTIFR)

The TIFR quantifies all incidents/accidents that resulted in an injury to an employee in the workplace. The LTIFR is an occurrence that resulted in lost time from work of one shift or more.

Health and Safety performance - Lost days from LTIs



● Lost days - Australia
 ○ Lost Day Frequency Rate (LDFR) - Australia



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Health and Wellness

As a company that is focused on creating a healthier life for all, we believe it is important to encourage our staff to live healthy lifestyles.

We encourage our employees to participate in company-supported wellness programs, pursue a healthy lifestyle, and integrate fitness and good nutrition into their daily lives. Our wellness programs are managed by our Human Resources team and leverage the expertise of external consultants and service providers. Mayne Pharma has a Wellness Committee in the US, which is an employee-led, cross-functional group that develops and leads a variety of wellness events and programs for employees at both the Greenville and Raleigh sites.

We encourage our employees to participate in company-supported wellness programs, pursue a healthy lifestyle, and integrate fitness and good nutrition into their daily lives

The wellness programs offered in Australia and the US include:

- Corporate sponsored Fitbit. The Company subsidised the purchase of Fitbits by employees and offered Fitbit challenges and competitive “step” contests, allowing teams and individuals to win prizes and awards.
- Resources to support mental health, healthy lifestyles and wellbeing through a mix of onsite face to face and online lectures, webinars, newsletters and other multimedia.
- Onsite medical clinic in Greenville offered two days per week for staff.
- Massage therapist visits.



***‘Fit Friday’
in Raleigh***

- Weekly group exercise programs, including yoga, at our US sites.
- Access to professional health assessments and medical services such as influenza vaccinations.
- Corporate support for employee participation in organised activities such as the Life Be In It Corporate Cup (South Australia).
- Access to an external Employee Assistance Program (EAP) to provide short term free of charge professional and confidential counselling and support services for employees and their families.
- Partnerships with external health funds to provide private health insurance options for employees and their families.

Offering our employees wellness benefits not only promotes healthy lifestyles and increases engagement, but also contributes to building a sustainably healthy community.



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Diversity

The Board recognises that a diverse and inclusive workforce is not only good for our employees but also good for business. Diversity enables Mayne Pharma to attract and retain talented people, create more innovative solutions and be more flexible and responsive to our customers' and shareholders' needs.

Mayne Pharma supports employees to achieve an appropriate work-life balance, promotes and rewards employees based on skills, experience and merit and ensures the workplace is free from discrimination and harassment.

The Company's approach to diversity includes a framework that helps the Company achieve the following:

- access to the broadest pool of available talent;
- a welcoming workforce culture that embraces diversity at all levels;
- utilisation of recruitment practices that ensure a fair and equitable selection process at all levels where candidates are assessed on the basis of skills and capabilities;
- ensure there is no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation;
- improved employee motivation and engagement; and
- enhanced teamwork and innovative solutions.

The Group's approach to diversity is underpinned by practical objectives to ensure that all of its employees have equal opportunity to demonstrate their talents, commitment and results. The Company measures its progress against these objectives and reports these each year in the [Corporate Governance Statement](#) which is included on the Mayne Pharma website. The diversity objectives are outlined on the opposite page.

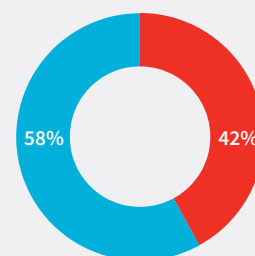
In 2016, 42% of the workforce and 37% of management positions were held by females. At the most senior leadership level 30% were female. In September 2016, Mayne Pharma appointed its first female Director to the Board.

In the US, the Company has an Affirmative Action Plan. One aspect of this plan is to assess opportunities for social inclusion of minorities and protected groups (eg veterans, people with disabilities, etc) against market availability. Goals have been developed to attract qualified applicants in identified under-employed groups.

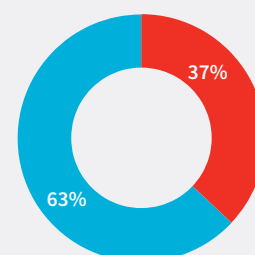
Gender diversity



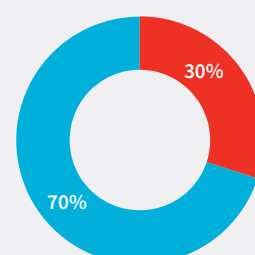
All employees



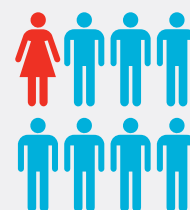
Management



Senior Executive¹

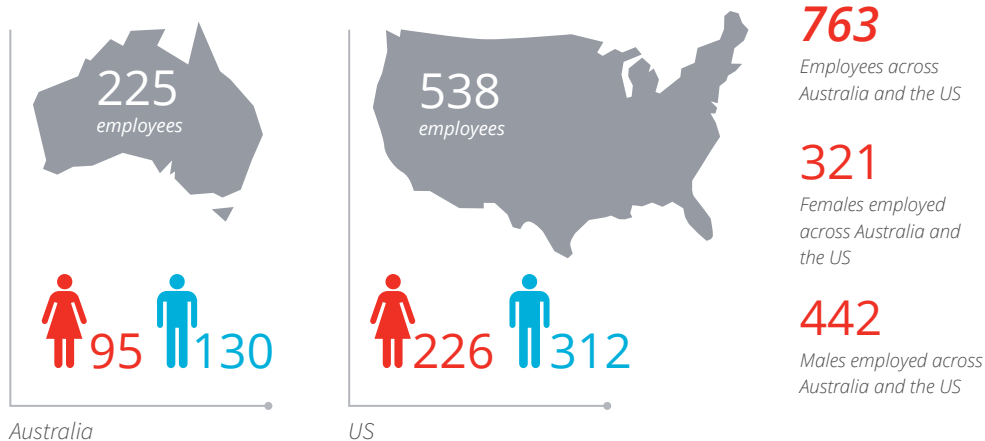


Mayne Pharma Board

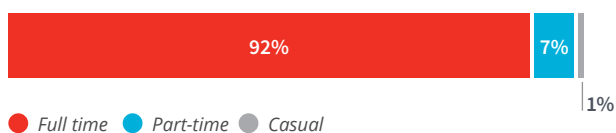


1. Senior executive captures all members of the Corporate Executive Committee

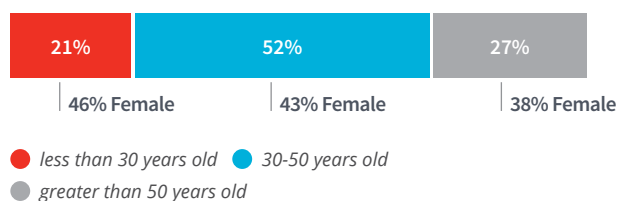
Our employees by the numbers



Employees by Employment type (%)



Employees by age group (%)



Our diversity objectives

OBJECTIVES	MEASUREMENT
Equal opportunity employer Our recruitment practices are fair and equitable at all stages and candidates are assessed on the basis of their skills and capabilities for the position and cultural fit with the business	We endeavour for: <ol style="list-style-type: none"> all selection processes and decisions to include both male and female representatives, and at least 1 female and 1 male will be invited to participate in the interview process, where appropriately skilled candidates have applied.
Equal gender participation We seek to maintain diverse participation at all levels	We endeavour for equal participation, allowing for a 10% variance either way. We will therefore seek to maintain a balance of at least 40% females and 40% males, in both management and non-management positions.
Equal opportunity for development High potential employees have equal opportunity to development programs to build a diverse pipeline of talent for succession opportunities	We endeavour for equal development opportunities, allowing for a 10% variance either way. We will therefore seek to maintain a balance of at least 40% females and 40% males, for participation in leadership or future leadership development program opportunities.
Equal gender remuneration Employees will be paid appropriate remuneration, based on their level of experience, achievements and competencies for their role	Undertake an annual pay equity analysis for employees in the same roles, and if any issues are identified, resolutions are put in place.



Product Pricing and Accessibility

Mayne Pharma is committed to providing affordable medicines and helping patients have a better quality of life.

Access to medicines continues to be one of the greatest barriers to life expectancy globally, with many of the world's population without access to essential medicines.

Mayne Pharma develops, manufactures and markets high quality generic and innovative branded products that can offer patients improved access and affordable options to medications that enhance lives.



In the US, generic prescription drugs saved American consumers US\$227 billion in 2015, according to the [Association for Accessible Medicines](#) and generics now represent nearly 90 percent of all prescriptions filled each year. Mayne Pharma has a track record of pharmaceutical innovation for developing new products that offer patients greater access to more affordable medications.

During 2016, the Company received two significant US FDA product approvals - dofetilide capsules, the first generic alternative to Pfizer's Tikosyn® brand and Doryx® MPC, a new product in the Doryx® family. These products have provided new treatment options and more choices in terms of medication affordability.

Dofetilide capsules

In June 2016, Mayne Pharma received FDA approval for the first generic alternative to Tikosyn® (dofetilide) capsules – an antiarrhythmic agent used to prevent irregular heartbeats such as atrial fibrillation and atrial flutter. Mayne Pharma was awarded 180-days of market exclusivity as it was the first company to file a substantially complete ANDA containing a Paragraph IV certification.

Mayne Pharma's generic product was priced to our customers at a >50% discount to the brand list price, delivering immediate savings to patients and payers. It also led to Pfizer launching its own authorised generic after our product was launched. In addition, a \$0 patient savings card was made available to eligible patients to further improve medication affordability.

Within four months of launch, Mayne Pharma's product captured more than 50% prescription share of the total dofetilide market¹ against Pfizer's Tikosyn® brand and the authorised generic. We estimate the launch of Mayne Pharma's generic dofetilide capsule has saved the US healthcare system tens of millions of dollars. These savings have been realised more than two years ahead of the Tikosyn® patent expiry in October 2018.

1. IMS Health, US Weekly dofetilide prescription volume, data up to week ending 21 October 2016

Doryx® MPC tablet

In May 2016, Mayne Pharma received approval for a new formulation of doxycycline - Doryx® MPC, which incorporates a modified polymer coat designed to further retard the release of doxycycline in the acidic environment of the stomach. The new polymer coat further delays absorption of Doryx® MPC into the gastrointestinal tract by approximately 15 minutes.

Doryx® MPC was launched in August 2016 and was priced 30% lower than comparable doses of the original Doryx® brand. A patient savings card with a \$0 copay was also offered to eligible patients. The Company chose to lower the price of Doryx® MPC to allow broader managed care coverage for acne patients and enhance accessibility for patients.

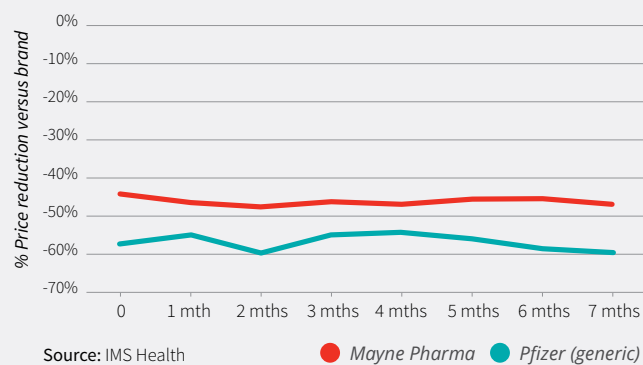
Generic launch case studies

Mayne Pharma has a successful track record of pharmaceutical innovation to develop new generic drugs that offer patients greater access to more affordable medications.

The charts on the right hand side outline three recent examples of generic launches by Mayne Pharma that have resulted in the market accessing more affordable medications.

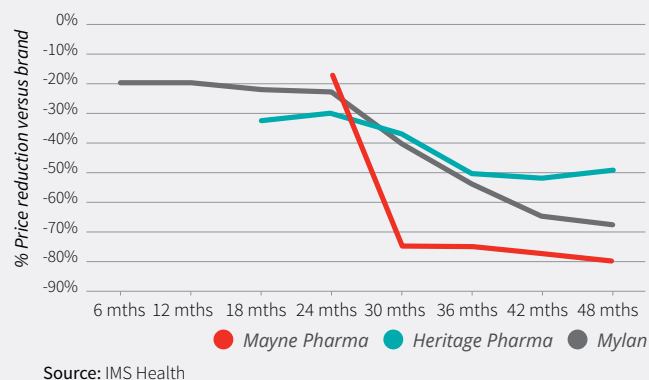
The charts outline the average price reduction in the IMS Health net selling price per unit versus the brand price in the quarter prior to generic competition.

500mcg dofetilide Net Selling Price (NSP) reduction since generic market formed



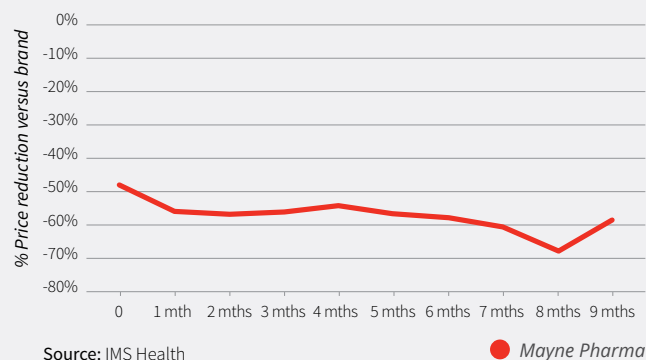
Dofetilide 500mcg capsules was launched in the US in June 2016 and was the 1st independent generic approval.

150mg doxycycline hyclate delayed-release NSP reduction since generic market formed



Doxycycline delayed release 150mg tablets was launched in the US in April 2014 and was the 3rd generic to enter the 150mg market

4m/4mg noradrenalin injection NSP reduction since generic market formed



Noradrenalin 4mg/4ml injection was launched in March 2016 in Australia and was the first generic approval and launch. This is a non Pharmaceutical Benefits Scheme (PBS) listed product.



Product Quality and Safety

Mayne Pharma is committed to the safety of our patients as they use the medications we develop, manufacture and market and as they participate in clinical trials to test medicines in development.

Mayne Pharma has a solid track record of quality and safety and we continuously invest in embedding a culture of quality and safety at all levels of our company. The Company has a strong history of compliance with applicable laws and is committed to delivering quality products and services which comply with all relevant regulatory and customer requirements.

Mayne Pharma aims to do this by:

- Maintaining the right level of skill and experience within our organisation to manage and grow the quality system with responsibilities clearly defined;
- Regular review of quality systems to ensure currency and efficiency via Management Review and Continuous Improvement strategies; and
- Appropriate risk based controls over all management and GxP (good (anything eg. manufacturing) practice) including but not limited to adequate qualification of all facilities, equipment, processes, procedures, test methods and suppliers.

In the six months to 31 December 2016, 36% of the products sold by Mayne Pharma (by value) were manufactured at our facilities in Greenville, North Carolina and Salisbury, South Australia. The remaining products were sourced from our partners around the world. Our external network of partners includes active ingredient manufacturers, contract manufacturing organisations, packaging manufacturers, distribution partners and suppliers and manufacturers of other supplies used in the production of our medicines.

The percentage of internally manufactured product has decreased substantially over the past year due to the recent Teva portfolio product acquisition. Over time, up to eleven of the acquired products will be transferred into our facilities and this will accelerate utilisation of manufacturing capacity and enable additional margin to be captured over time, improving overhead recovery.

Mayne Pharma adheres to current Good Manufacturing Practice (cGMP) in its operations related to product manufacture, along with Good Clinical Practices (GCP); Pharmacovigilance and Regulatory Affairs operations for the purpose of measuring compliance with health authority regulations, Mayne Pharma policies and industry standards. Audits are undertaken at our own locations and at third party partner facilities.

We conduct due-diligence site visits before agreeing to partner with a third party. Choosing suppliers involves a rigorous assessment of their facilities, past track record, capacity and ability to maintain continuity of supply.

Our facilities along with our partner facilities are inspected regularly by health authorities around the world including the Food and Drug Administration (US) and the Therapeutic Goods Administration (Australia).

Mayne Pharma has procedures for monitoring product complaints and drug safety on marketed products and relevant employees and contractors undertake regular training. During product development, the safety of products are assessed throughout each stage via either clinical studies or other equivalence testing to existing products on market, together with comprehensive stability testing. The data from these studies are submitted to the relevant regulatory agency for approval prior to launch. From launch all products have a "Patient Information" leaflet available to explain known safety issues with each product. Customer health and safety is regularly assessed through various quality reporting systems including monthly management reporting, quarterly Quality

Mayne Pharma has a solid track record of quality and safety and we continuously invest in embedding a culture of quality and safety at all levels of our company

Management Review, biannual Extended Safety Team meetings and Annual Review and trending of Product Complaints.

In 2016, Mayne Pharma had 51 regulatory and customer inspections / audits across the Australian and US manufacturing sites which resulted in zero critical observations. Eight of the audits were for commercial products with the remainder being for clinical development or raw material testing by Metrics Contract Services' customers.

During the year we conducted 48 quality audits of suppliers across the globe designed to ensure the materials and services provided by our partners meet our quality standards.

In 2016, we initiated a recall of Bromfenac in the US. This recall was a Class II FDA recall because of a new standard imposed by the FDA.

Product recalls

	2015	2016
Number of product recalls	0	1
Annual % of units sold and recalled	Nil	<1%

Ethical Sourcing

Our Business Code of Conduct outlines our values and the standards we expect from our partners. These responsibilities represent the foundation of our company and what we stand for, and are the basis for our continued success. We seek to prevent or mitigate adverse human rights practices that are linked to our operations, products or services.

Our commitment is formalised and manifested through our policies, including our Business Code of Conduct and our governance and EHS systems. We endeavor to ensure our procurement processes are fair and equitable and that our expectations, requirements and relevant policies are clearly communicated.

We expect that our suppliers:

- engage in lawful business practices;
- uphold ethical employment and management practices;
- minimise the impact on the environment; and
- provide a safe and healthy workplace.

Mayne Pharma works with its suppliers and external partners to communicate its expectations on ethical standards, for example, by ensuring that written agreements with suppliers and external partners contain obligations to comply with anti-bribery rules and regulations such as the Foreign Corrupt Practices Act (FCPA).

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Overview

Mayne Pharma understands the value of operating its business sustainably and protecting the environment in which we operate. To achieve this, Mayne Pharma uses an Environment, Health and Safety (EHS) management system, supported by policies, management plans, standard work practices and guidelines.

Our operations are subject to various EHS laws and regulations and where required we maintain EHS licenses and registrations in compliance with applicable regulatory requirements. The Company has processes in place to monitor for changes to regulatory requirements and ensure ongoing compliance with any new requirements.

Primarily, our EHS policies and procedures are designed to ensure or exceed compliance with all EHS regulatory requirements and to continuously improve the health and safety of our workplaces and the environmental sustainability of our operations

Our EHS function continues to refine and improve our standards, processes and performance through the ongoing development and maintenance of an EHS management system. This system focuses on identifying and assessing hazards and effectively managing EHS risks by applying sound risk management principles.

We monitor EHS outcomes on a regular basis and report performance data such as injury rates, utilities consumption, waste discharges and emissions. Operating sites in Salisbury and Greenville are subject to periodic inspections by EHS regulators; several inspections occurred during the year by the relevant authorities with no violations or citations recorded.

Going forward, Mayne Pharma will continue to develop and improve sustainability awareness and performance. We will formalise and implement sustainability KPIs for all our manufacturing operations and develop further our understanding of the impacts we have on the environment.



Energy Use and Efficiency

Energy consumption

Mayne Pharma's major energy sources are electricity and natural gas across our manufacturing sites. During 2016 a number of energy consumption reduction initiatives were undertaken, including an upgrade to climate control at a storage facility, and new transformers & voltage optimisation at the Salisbury manufacturing site which has had an impact on scope one and two energy consumption respectively.

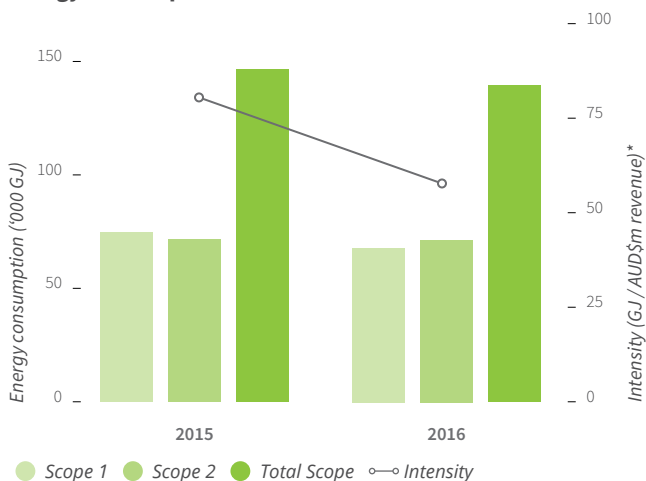
Greenhouse Gas (GHG) Emissions

Emissions from our manufacturing sites are subject to reporting to various environmental agencies and we are required to notify those agencies in the event of material changes to plant, equipment or processes that may increase the risk of environmental harm arising from operations.

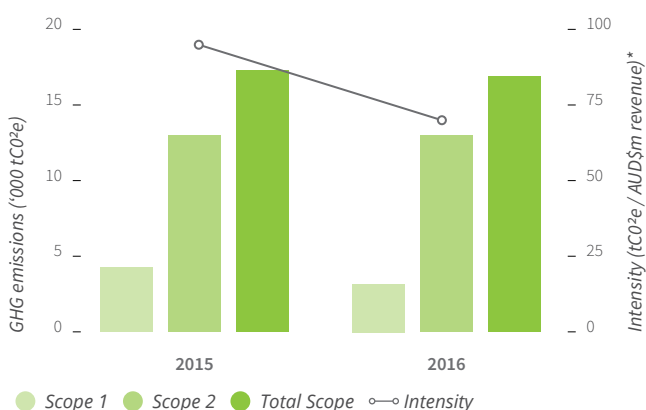
In Australia, our Environmental Authorisation is issued by the Environment Protection Authority (EPA) for 5 years and the Salisbury site is required to provide an annual return detailing emissions volumes as specified in the National Pollution Inventory (NPI) reporting standards and any material changes to operations. Emissions are monitored as part of mandated NPI reporting requirements, which are submitted to the NPI and also used for the EPA annual return process.

Mayne Pharma has engaged external consultants to assist to monitor GHG emissions for existing production, with a view to implement strategies for emissions reduction in the future. In addition, both Greenville and Salisbury sites are undergoing major expansion projects, due for completion in 2018. These projects utilise GHG efficient technologies in consideration of our global emissions footprint.

Energy consumption trends



Greenhouse Gas (GHG) emissions trends



Note: Conversion factors derived from: National Greenhouse Accounts (NGA) Factors, Department of the Environment, Cth. August 2015. US Scope 2 factors derived from: eGRID 2014 v2, released 27/Jan/2017 epa.gov.energy/egrid. All other conversions utilising SI Units

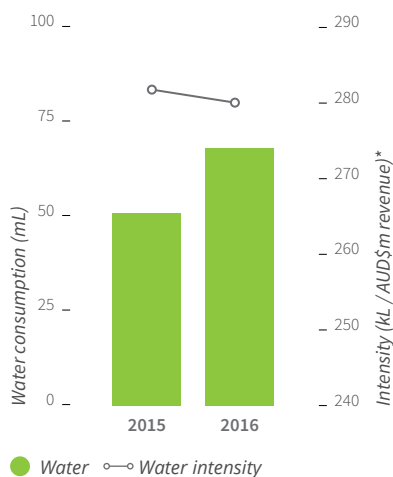
*Intensity trend calculations include revenue from internally manufactured products only





Water and Waste Management

Water consumption trends



Water usage

Water is critical to the manufacturing of pharmaceutical products to ensure plant and equipment is in a clean and sanitary state to comply with GMP requirements and water used in the processing of our products meets purity and quality standards. Mayne Pharma will be developing a formal water management approach across its operations in 2017 with a view to identifying opportunities to reuse and reduce the amount of water consumed.

Waste management

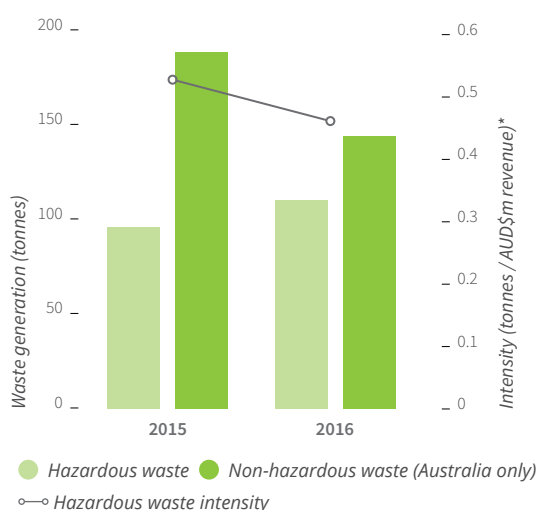
Mayne Pharma is committed to responsible waste management. In the pharmaceutical industry, the extent to which waste can be recycled is limited as wastewater, manufacturing wastes, plant consumables (ie HEPA filters) and packaging materials may contain pharmaceutical compounds, cleaning chemicals and other reagents and residues generated in product development and production processes.

We are obligated to ensure pharmaceutical compounds such as controlled substances (ie Schedule 8 medicines in Australia or CII-CIV in the US) are completely destroyed under supervised conditions, which requires the use of high temperature incineration at an offsite third party facility.

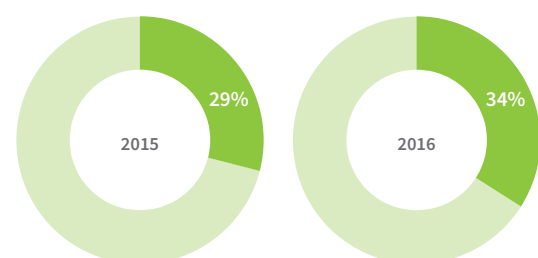
To the extent possible waste streams are separated to remove uncontaminated cardboard, soft plastics, paper and other recyclable materials from general waste to minimise the amount of waste transferred to landfill or destruction.

During the introduction of new products, potential sources of waste are considered and procedures and processes are developed and implemented to minimise waste. During development and scale up of new products, wastes identified as potentially harmful to the environment are retained and chemically tested to confirm concentrations and approval is sought from the relevant regulator prior to discharge to trade waste or destruction.

Waste generation trends



Waste recycling/reuse (AU data only)



*Intensity trend calculations include revenue from internally manufactured products only

Mayne Pharma is continuously monitoring and assessing ways to effectively manage and treat waste produced from its operations. Our sites are working with third party waste contractors to identify opportunities for improved recycling systems to improve performance in this area.

Manufacturing sites have water quality parameters for liquid trade waste to ensure waste water is suitable for discharge, in accordance with regulatory licensing. Trade waste is sampled for both water quality (for example Total Dissolved Solids, Biochemical Oxygen Demand), and specific chemicals (for example Phosphorous and Nitrogen) on a regular basis. These parameters are monitored on site, by independent third-party consultants and by regulatory authorities to ensure compliance with licensing agreements.

Audits of the trade waste management system are periodically conducted by regulatory authorities to monitor compliance to relevant standards and where necessary, corrective actions are implemented to address any observations made.

• Case study

Sustainable Design Features at Mayne Pharma's new Greenville solid oral dose development and manufacturing plant

Lighting:

The building layout maximises the use of natural light during daytime. LED and energy efficient lighting has been installed to reduce energy consumption.

Heating and cooling:

- 100% outside air HVAC has heat reclaim recovery systems.
- All heating and steam boilers are natural gas fueled.

Water and waste:

- Reverse Osmosis reject water is being recovered and used for cooling tower water.
- All air handling unit condensate drain water is being recovered and used for cooling tower water.
- Process waste water neutralisation system.



Cooling towers under construction at Mayne Pharma's new Greenville manufacturing plant

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Economic Contribution

Strong economic performance enables us to invest in our future growth and to continue to support communities through charitable donations. Our growth strategy and our investments are discussed in our [2016 Annual Report](#). An experienced management team, active risk identification and management, coupled with financial discipline and strong execution of strategy support our financial performance.

2016 has been another successful year for Mayne Pharma on the back of new product launches, product acquisitions and increased market penetration of key product franchises. Our full year FY16 results have been published in the 2016 Annual Report.

In terms of the 2016 calendar year, we achieved revenue of \$434.9m and net profit after tax of \$90.9m. We paid tax of \$36.1m in the US and Australia and total compensation to employees was \$95.9m.

Community Investment

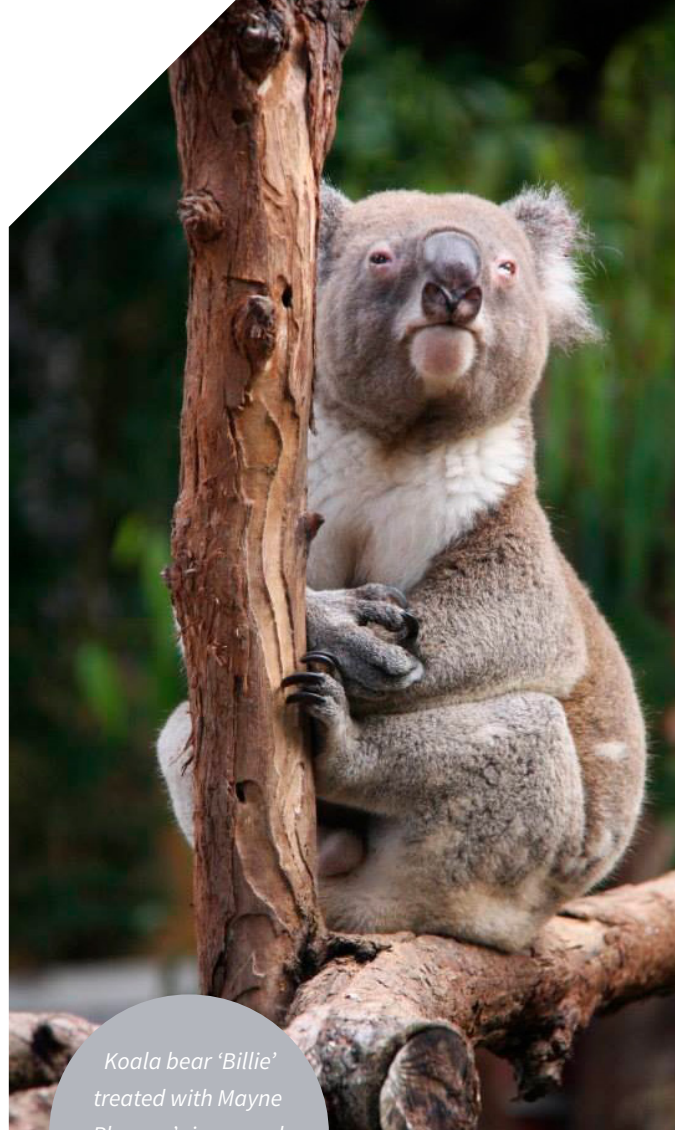
In 2016, Mayne Pharma contributed to community activities both financially, in-kind and by donating time. Mayne Pharma supports several not-for-profit organisations that contribute to community based initiatives, support disadvantaged sections of society, conduct educational and training programs and promote healthy lifestyles.

Some of the charitable activities Mayne Pharma supported over 2016 include:

- **United Way Employee Campaign (US)** – The United Way provides a platform for elective employee gifts to charitable donations via payroll deduction. The company sponsors an “Agency Fair” that allows non-profit agencies associated with the United Way to come on site and meet directly with employees about their mission and programs. Employees can either give directly to a designated agency or give to the general United Way fund. The company matches all donations.
- **Red Kite Charity (Australia)** – Mayne Pharma became a State Sponsor during the year. Red Kite provides support to families affected by childhood and adolescent cancer.
- **Children’s Park rehabilitation (US)** – The Company established its own project in funding the rehabilitation of a local children’s park and playground and the establishment of a Mayne Pharma sponsored “Born Learning Trail” at the park, designed to provide an applied educational experience at the park for children and their parents.
- **Mayne Pharma Scholarships (US)** – Mayne Pharma provides US\$1,000 scholarships for local students and Mayne Pharma employee children who are entering post-secondary educational programs. The scholarships are competitive based on cumulative academic performance and service to the community. Preference is given to students intending to pursue degrees in science and technology.

Mayne Pharma has a Community Committee operated by employees in the US, which is a cross-functional group of employees that manage and direct the charitable contributions of the organisation

- **Breast Cancer Awareness** – Company sponsored a Fitbit challenge in which the company pledged to donate US\$0.25 for every mile walked in the US. A variety of raffles were also conducted in which employees purchased tickets for a chance to win company sponsored prizes and gift certificates.
- **Blood Drives** – Quarterly employee blood drives.
- **Dermatology in East Timor** – a charity set up by dermatologists from the Skin and Cancer foundation in Melbourne. Mayne Pharma donated supplies of the much needed oral antifungal Itraconazole (Lozanoc®) to be used in their outpatient clinics.
- **Faculty of Veterinary Science, University of Sydney** – Koalas can contract a lethal fungal infection called cryptococcosis. Working in conjunction with vets at University of Sydney, Mayne Pharma supplied Lozanoc to help treat sick Koalas in Cairns and Sydney's Taronga Zoo.
- Mayne Pharma (Australia) sponsors employee-driven charity work by matching donations dollar-for-dollar. During the calendar year, this included sponsorship of:
 - **The Country Fire Service** – volunteer emergency services organisation specialising in first response to emergencies such as fires, natural disasters, and vehicle accidents



Koala bear 'Billie' treated with Mayne Pharma's improved formulation of itraconazole

- **The Movember Foundation** – a global organisation, raising awareness of leading causes of preventable, reduced life expectancy in men, such as, prostate and testicular cancer, and mental health issues.
- **The Smith Family** – national education-oriented charity, supporting disadvantaged children to participate fully in their education, giving them the best chance at breaking the cycle of disadvantage.

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Research, Education and Training

Mayne Pharma continues to support and recognise researchers and young scientists. We encourage students to pursue higher education in science programs, sponsor awards, provide work placements for students and collaborate on education and research. Some of the Company's alliances include:

Flinders University

- Collaboration on clinical trials to investigate the effectiveness of extended release morphine sulphate to treat refractory dyspnea (chronic breathlessness)
- Program funded through \$860,000 National Health and Medical Research Council grant from the Australian Government along with financial contributions and in kind contributions from Mayne Pharma
- Aim of the study is to improve prescribing habits and palliative care services in Australia

University of South Australia

- Collaboration on project work with the School of Pharmacy
- Sponsorship of seven different prizes and awards each year
- Provision of work placements for students

East Carolina University

- Providing input into curriculum development and course design within the Chemistry Department
- Underwriting 20 teaching assistant positions annually in support of the lab based general chemistry course
- Providing staff to serve as instructors and lab support in GMP Chemistry course
- In 2016, provided 12 internships to students in science and engineering majors
- Donated two industrial grade chemistry scales for use in introductory chemistry course

NCEast Alliance

- Community and economic development of the region with major focus on building a critical mass of life science industries and developing tools for workforce development in the areas of Science Technology Engineering and Math (S.T.E.M.)
- Participation in their S.T.E.M. program, sponsored the development of a lab in a local middle school
- Providing opportunity for employees to visit middle schools to do basic instruction in chemistry and discuss careers in science with students



Case study

Mayne Pharma named Pitt County Industry of the Year in 2015/16

Each year, the Pitt County Development Commission recognises a manufacturer or distributor that best represents the community as a model corporate citizen.

Mayne Pharma established its presence in Pitt County — and the United States — when it acquired Metrics Inc. in 2012. Founded in Greenville in 1994, Metrics started as a laboratory providing analytical chemistry support services to pharmaceutical companies. The company steadily grew into a full-service pharmaceutical development and manufacturing organisation that also develops, manufactures and markets branded and generic drug products.

In September 2015, Mayne Pharma announced a US\$65-million investment to significantly expand facilities and equipment at its Greenville site. The expansion will include a new, 11,600 square metre (125,000-square-foot), large-scale oral-dose manufacturing facility, as well as an employee and visitor centre, conference rooms, training space, cafeteria, and fitness centre. Plans also include repurposing existing space to support the rapid growth of Metrics Contract Services.

The investment in US development and manufacturing capacity and capability — as well as a robust pipeline of branded and generic products — positions Mayne Pharma as a global leader in advanced oral drug delivery systems.

The Company anticipates hiring 100 scientists, quality assurance specialists, manufacturing operators and technicians during the life of the expansion project.

In addition to the jobs and capital investment Mayne Pharma has announced, the Company makes significant



community-related investments. The Company has a sizeable sponsorship budget for large and small requests for local charitable causes and youth athletic teams. In addition to financial contributions, employees provide thousands of hours of in kind support. Mayne Pharma is also a major corporate partner of Uptown Greenville and a major sponsor of PirateFest, the region's signature community event, which draws approximately 30,000 people each year to celebrate North Carolina's rich history.

Mayne Pharma is a key industrial partner for East Carolina University (ECU), providing significant support to the chemistry program, including GMP coursework development. The relationship with ECU is ongoing and helps students by teaching skills useful for careers in the pharmaceutical industry and also provides the company with a valuable pipeline of industry-relevant job candidates.

Mayne Pharma, along with other industry partners, is also a contributor to the development of the Biopharmaceutical Work Force Development and Manufacturing Center of Excellence, a Golden Leaf-funded collaboration between ECU and Pitt Community College to prepare a qualified pharma workforce for companies in North Carolina.

Our Approach



Our People



Our Products



Our Operations



Our Contribution



GRI Index



General Standard Disclosures

Disclosure	Description	Report Section / Detail	Page No.
Organisational profile			
102-1	Name of the organization	The Mayne Pharma Story	Pages 6-9
102-2	Activities, brands, products, and services	The Mayne Pharma Story	Pages 6-9
102-3	Location of headquarters	Corporate Information	Page 41
102-4	Location of operations	The Mayne Pharma Story	Pages 6-9
102-5	Ownership and legal form	Corporate Information	Page 41
102-6	Markets served	The Mayne Pharma Story	Pages 6-9
102-7	Scale of the organization	The Mayne Pharma Story	Pages 6-9
102-8	Information on employees and other workers	Our People	Pages 18-23
102-9	Supply chain	The Mayne Pharma Story	Pages 6-9
102-10	Significant changes to the organization and its supply chain	None	–
102-11	Precautionary Principle or approach	In product quality and environmental management, we adhere to the precautionary principle	–
102-12	External initiatives	Governance, Compliance & Risk Management	Pages 14-17
102-13	Membership of associations	The two key trade associations we engage with are AHMADA in Australia and GPHA in the US	–
102-14	Statement from senior decision-maker	Chairman and Managing Director's Report	Page 5
102-16	Values, principles, standards, and norms of behaviour	Governance, Compliance & Risk Management – Governance framework	Page 14
102-18	Governance structure	The Mayne Pharma Story	Pages 6-9
102-40	List of stakeholder groups	Sustainability at Mayne Pharma	Pages 10-13
102-41	Collective bargaining agreements	Approximately 30% of the workforce are represented by an independent trade union or covered by a collective bargaining agreement	–
102-42	Identifying and selecting stakeholders	Sustainability at Mayne Pharma	Pages 10-13
102-43	Approach to stakeholder engagement	Sustainability at Mayne Pharma	Pages 10-13
102-44	Approach to stakeholder engagement	Sustainability at Mayne Pharma	Pages 10-13

<i>Disclosure</i>	<i>Description</i>	<i>Report Section / Detail</i>	<i>Page No.</i>
102-45	Key topics and concerns raised	Captures all entities 100% control as outlined in our Annual Report	–
102-46	Key topics and concerns raised	About this report, Sustainability at Mayne Pharma	Page 2, Pages 10-13
102-47	Entities included in the consolidated financial statements	Sustainability at Mayne Pharma	Pages 10-13
102-48	Defining report content and topic Boundaries	As this is the first report, not applicable	–
102-49	List of material topics	As this is the first report, not applicable	–
102-50	Restatements of information	About this report	Page 2
102-51	Reporting period	About this report	Page 2
102-52	Date of most recent report	About this report	Page 2
102-53	Reporting cycle	About this report	Page 2
102-54	Contact point for questions regarding the report	About this report	Page 2
102-55	Claims of reporting in accordance with the GRI Standards	GRI content Index	Page 36
102-56	GRI content index	No external assurance was sought for this report	–
103-1	External assurance	Sustainability at Mayne Pharma	Pages 10-13
103-2	Explanation of the material topic and its Boundary	Sustainability at Mayne Pharma	Pages 10-13



Specific Standard Disclosures

Disclosure	Description	Report Section / Detail	Page No.
Economic			
201-1	Direct economic value generated and distributed	Select data included in Our Contribution. Other data to be collected in future reports	Page 32
205-1	Operations assessed for risks related to corruption	Governance, Compliance and Risk Management	Pages 14-17
205-2	Communication and training about anti-corruption policies and procedures	Governance, Compliance and Risk Management	Pages 14-17
205-3	Confirmed incidents of corruption and actions taken	No confirmed incidents of corruption	–
206-1	Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	Governance, Compliance and Risk Management	Pages 14-17
Environmental			
301-1	Materials used by weight or volume	This information is not currently available	–
302-1	Energy consumption within the organisation	Our Operations – energy use and efficiency	Page 29
302-3	Energy intensity	Our Operations – energy use and efficiency	Page 29
303-1	Water withdrawal by source	Our Operations – water and waste management	Page 30
305-2	Energy indirect (Scope 2) GHG emissions	Our Operations – GHG emissions	Page 29
305-3	Other indirect (Scope 3) GHG emissions	This information is not currently available	–
305-4	GHG emissions intensity	Our Operations – GHG emissions	Page 29
306-1	Water discharge by quality and destination	Our Operations – water and waste management	Page 30
306-2	Waste by type and disposal method	Our Operations – water and waste management	Page 30
306-3	Significant spills	No significant environmental events in 2016	–



Disclosure	Description	Report Section / Detail	Page No.
Social			
403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	Our people - Health and Safety	Pages 18-19
403-3	Workers with high incidence or high risk of diseases related to their occupation	This information is not currently available	–
405-1	Diversity of governance bodies and employees	Our people – Diversity	Pages 22-23
408-1	Operations and suppliers at significant risk for incidents of child labour	Product quality and safety	Pages 26-27
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labour	Product quality and safety	Pages 26-27
414-1	New suppliers that were screened using social criteria	Product quality and safety	Pages 26-27
414-2	Negative social impacts in the supply chain and actions taken	Product quality and safety	Pages 26-27
416-1	Assessment of the health and safety impacts of product and service categories	Product quality and safety	Pages 26-27
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	Product quality and safety	Pages 26-27

Additional information

Intellectual Property

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Glossary

ANDA – Abbreviated New Drug Application. An application to market a generic drug in the US. Generic drug applications are called “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

API – Active Pharmaceutical Ingredient. An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

BA – Bioavailability. A measure of the fraction of a drug that enters the systemic blood circulation after oral administration.

BE – Bioequivalence. Two drug products are considered bioequivalent if they exhibit the “same” C_{max}, T_{max} and AUC in a properly powered pharmacokinetic study. In other words the two drug products have the plot of “drug concentration in plasma” against “time”. The actual definition of “same” when applied to the pharmacokinetic parameters varies from country to country. If two drug products are bioequivalent then it is assumed that they are therapeutically equivalent. A

For further information on Mayne Pharma’s products, refer to the product section of the Company’s website, [https://www.maynepharma.com/products/us-](https://www.maynepharma.com/products/us-products/)

[products/](https://www.maynepharma.com/products/us-products/) or <http://www.maynepharma.com/products/australian-products/>.

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bioequivalence study is the cornerstone of an ANDA or any generic drug application, because for the reasons given here, bioequivalence obviates the need to perform long and expensive clinical studies.

DR – Delayed Release. A drug product (typically oral) that is not intended to release the drug substance immediately after ingestion. The delay is commonly related to change of pH in the gastrointestinal tract (“enteric coating”) or less commonly may relate to a specific time after ingestion when the drug is released. Enteric coating is achieved by coating with polymers that are poorly soluble in low pH media (for example gastric fluid), but are soluble in media with pH values typically found lower in the intestine.

FDA – US Food and Drug Administration. The US FDA is responsible for protecting public health by assuring the safety, efficacy and security of, amongst other things, human drugs.

GMP – Good Manufacturing Practice

NDA – New Drug Application. When the sponsor of a new drug believes that enough evidence on the drug’s safety and effectiveness has been obtained to meet FDA’s requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may

be marketed in the US.

OTC – Over-the-Counter pharmaceuticals. Products that are considered safe and effective by the FDA and TGA for use by the general public without a doctor’s prescription.

PIV – Paragraph IV filing. A type of filing to support the approval of an ANDA submitted while the originator product is covered by a patent. The filing asserts that either the patents supporting the originator product are invalid or that they are not applicable to the product that is the subject of the ANDA.

PK – Pharmacokinetics. The study of the time course of the way the body handles drugs. There are four essential processes following a person’s ingestion of a tablet or other oral dosage form, collectively known as ADME processes (Absorption of the drug from the gut; Distribution of the drug into other body tissues; Metabolism of the drug to other chemicals (metabolites) and Elimination of the drug from the body). This time course is typically followed by taking blood samples from volunteers at time intervals following swallowing a tablet, and measuring the amount of drug and / or metabolites in the plasma. A plot can be constructed of plasma concentration against time from which various PK parameters such as C_{max}, T_{max} and AUC can be derived.

TGA – Therapeutic Goods Administration. The TGA is Australia’s regulatory authority for therapeutic goods.

Corporate information

DIRECTORS:

- Mr Roger Corbett, AO
(Chairman)
- Mr Scott Richards
(Managing Director and CEO)
- Hon. Ron Best
- Mr Bruce Mathieson
- Mr Ian Scholes
- Mr William (Phil) Hodges
- Prof Bruce Robinson
- Ms Nancy Dolan

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PRINCIPAL PLACES OF BUSINESS:

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ABN:

76 115 832 963

DOMICILE AND COUNTRY OF INCORPORATION:

Australia

LEGAL FORM OF ENTITY:

Public company listed on the Australian
Securities Exchange (ASX: MYX)

Our Approach



Our People



Our Product



Our Environment



Our Contribution



Our Performance



