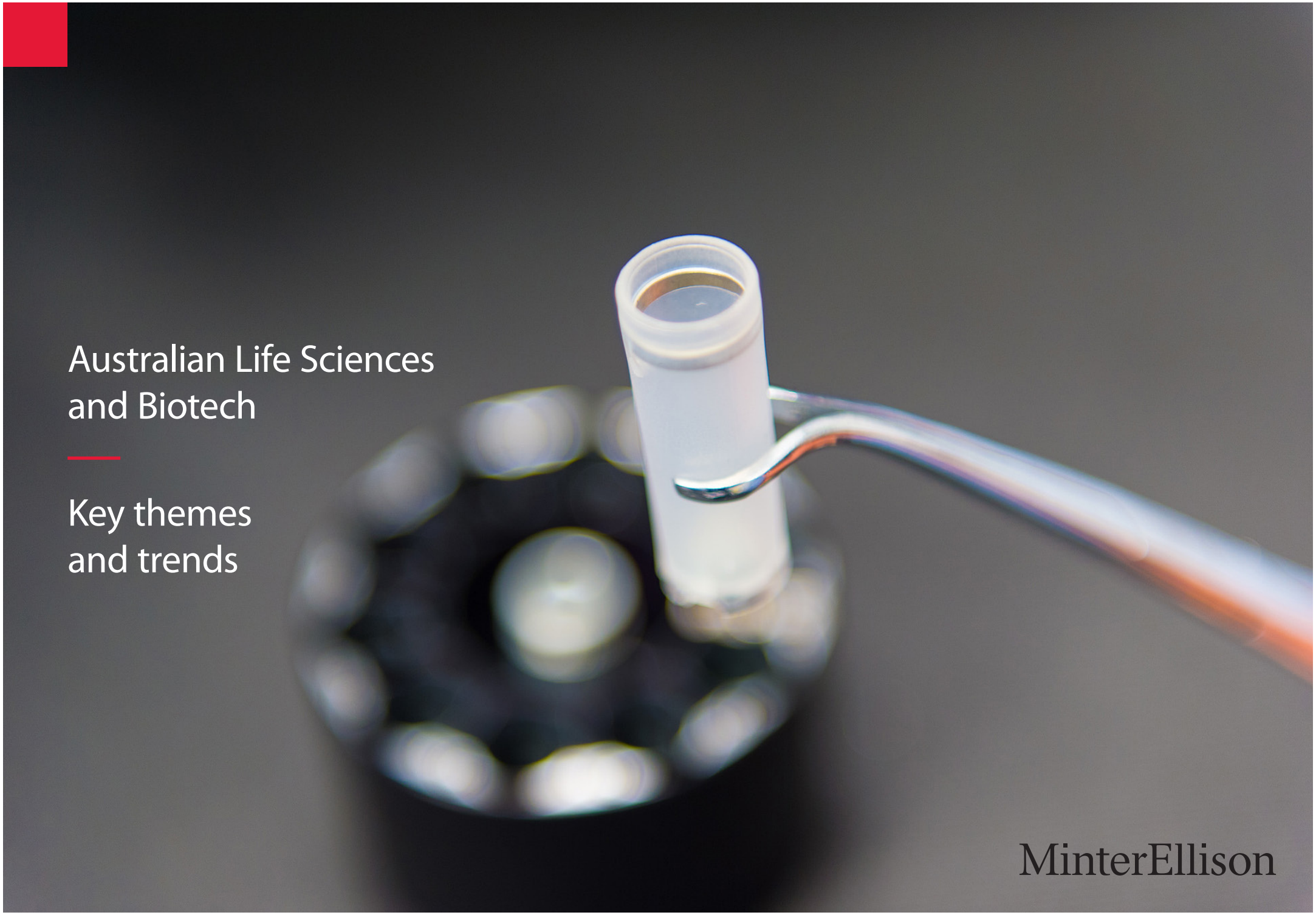


Australian Life Sciences and Biotech

Key themes and trends

MinterEllison

The Australian life sciences and biotech sector is likely to continue its resurgence over the next twelve months, with global trends driving strong M&A activity in life sciences and biotech M&A. We have identified 6 key themes for activity in this sector.

Opportunities and Challenges – 6 key themes

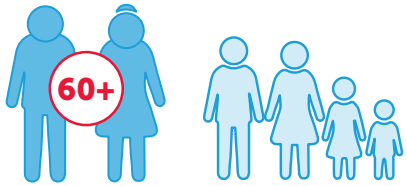
Three key opportunities

1. Demographic trend:

According to the Australian Institute of Health and Welfare, healthcare expenditure in Australia is growing faster than population growth and GDP growth. Further, data obtained from the Pharmaceutical Benefits Scheme (**PBS**) has revealed that during the period 2013 to 2015, the number of subsidised prescriptions in Australia rose by 1.25% and the number of non-subsidised prescriptions increased by 18.6%. Australia's ageing population continues to remain a key factor in driving the demand for healthcare and pharmaceutical products in Australia, with the median age having risen three years over the last two decades and the proportion of Australians aged 65 and over expected to increase rapidly. We believe that these industry dynamics will drive the growth of companies servicing the Australian industry. This, in turn, should lead to greater investment and opportunistic M&A, including in relation to life sciences, biotech and pharmaceutical companies whose technologies are vital in the treatment of aged patients.

Globally, the UN predicts that the proportion of people over 60 years old will increase at a rate that outpaces the growth of any other age group in what it calls 'one of the most significant social transformations of the twenty-first century'. This opens up important opportunities over the course of the next few years, particularly within China, which is likely to remain one of the most attractive markets for healthcare providers and pharmaceutical and biopharmaceutical companies.

The proportion of the 60+ age group will increase faster than any other age group



China's spend on healthcare is predicted to grow to $1 trillion in 2020. Many factors are fuelling this growth including:

- urbanisation
- healthcare reforms
- economic growth, and
- an increasing focus on health.

Above all, China's aged population is increasing significantly. China's 65 and over population, that accounted for an estimated 40% of the prescription drug market and up to 50% of the over-the-counter drug market in 2011, is predicted to triple to 329 million in 2050, larger than the population of the US today.

Chinese spending on health care predicted to be

$1 Trillion in 2020

This represents a substantial opportunity for industry players and investors looking to help meet the growing demand for healthcare and pharmaceutical products within China – and Australian companies are well placed to operate in this space.

According to the Department of Foreign Affairs and Trade, China is Australia's largest market for pharmaceuticals and this trend is expected to continue with the elimination of tariffs on pharmaceutical products by 1 January 2019. Pharmaceutical exports to China are also expected to continue increasing over the next five years as interest from China pushes medicinal pharmaceutical exports strongly out of the decline experienced from 2012 to 2015. China's recent interest in vitamins and supplements companies (including those in Australia and New Zealand) continues to grow as food safety and quality are key focuses for Chinese consumers. Australian vitamins and supplements companies have a strong reputation overseas, and as the Chinese elderly account for over 50% of sales of health foods including supplements, this opportunity, while already huge, is likely to grow. We expect a sustained increase of Chinese investment into Australian vitamins and supplements companies as they seek to service the growing market and vertically integrate their offerings.

The Chinese market also provides opportunities for other types of Australian healthcare and medical service providers due to the population's increasing focus on health. Spending for healthcare services in hospitals in China is predicted to grow from an estimated A$698 billion in 2017 to A$845 billion by 2018. The Australia-China Free Trade Agreement has enabled wholly Australian-owned hospitals to be established in China, so Australian medical service suppliers have an important role to play.

Case Study

China's continuing appetite for acquisitions in the healthcare, pharma and bio space, is demonstrated by the recent acquisition of Vitaco Holdings Limited, an Australian and New Zealand nutritional products company, by a Chinese consortium comprising entities controlled by Shanghai Pharmaceuticals and Primavera Capital. The transaction was effected by way of court-approved scheme of arrangement.

MinterEllison advised Vitaco on the transaction, which featured a number of innovative structures and provisions, and followed on from other transactions in the sector, including the acquisition of Swisse by Hong Kong-listed company Biostime International Holdings. These transactions highlight the demand for Australian brands and products in China, that are regarded as "clean and green" when compared with domestic produce.

This is further borne out by the intentions of Shanghai Pharma and Primavera for Vitaco. In the scheme booklet, they note that they propose to expand the distribution of Vitaco's products into potential new markets in the Asia Pacific region utilising Shanghai Pharma's extensive retail pharmacy distribution network, particularly in China.

2. Inorganic growth:

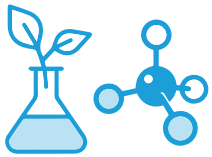
As the chemically-synthesised pharmaceutical pipeline dries up, large and mid-tier pharmaceutical companies have been turning to biopharmaceuticals to replace that value. However, internal biopharmaceutical pipeline value creation has been difficult. Internal R&D returns for original large biopharmaceutical companies continue to decline, from 7.3% in 2012 to 3.7% in 2016, and from 17.4% in 2013 to 9.9% in 2016 for their mid-tier counterparts. As a result, a majority of players in the pharmaceutical and biopharmaceutical industry will need to continue to implement external innovation strategies through M&A, looking outward to acquire value in a race for inorganic growth through bolt-on acquisitions.

Pharmaceutical and biopharmaceutical companies may be further encouraged by political movements to undertake M&A. Overseas, cash stockpiles may be boosted by a favourable cash repatriation plan and tax easing policy proposed by the US government and UK's period of monetary easing. This complements the industry's increasing appetite to invest in companies with lead assets at early stages of development. Traditionally, big players look to acquire concept-proven late-stage pipeline offerings. In the last two years, however, there has been significant increases in M&A exits in some emerging categories despite weaker overall M&A activity. For example, oncology focussed start-ups accounted for 20% of all pharmaceutical private market deals last year, which represents an increasing focus on improving cancer treatment. This included the second-largest venture capital-backed deal in history with AbbVie acquiring cancer therapeutics start-up Stemcentrx for US$10.2 billion. The industry is seeing some significant developments in the treatment of certain illnesses, and another category to watch for will be gene-based therapy, which includes genomics, gene-editing and genetic engineering applications.

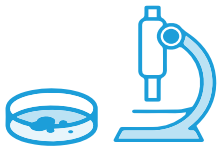
Examples of developments in the life sciences and biotech industries:

Advancements in genomics enabling the mapping and understanding of the structure, function and evolution of the human and agricultural genomes

Development of gene-editing and genetic engineering techniques like CRISPR/Cas9 to treat, and even cure, diseases



Use of biomasses and biofuels as replacements for fossil fuels



Rise of biologics and biopharmaceuticals for medical treatments

Where does Australia sit in this broader trend?

Australia is a leader in R&D in biotech. The 2016 Scientific American Scorecard placed Australia at no. 5 globally in an assessment of innovation potential in biotech. Australia is also in the top 10 most competitive locations for R&D development.

Today, we have one of the largest biotech industries in the world, home to over 480 biotech companies with an annualised industry revenue growth rate of 4% in the past five years and forecasted annualised growth rate of 4.3% to 2022.

Australia has one of the largest biotech industries in the world

There were over A$2 billion of biotech deal flows in 2016 and Australian biotech companies have raised over A$1 billion in 2015 and 2016 in capital raisings including IPOs and backdoor listings. Deal value looks set to continue for the coming year.

Austrade estimates investment in Australian clinical trials by pharmaceutical, biotech and medical devices in company to be continue at A$1 billion annually for the next few years, 20% of which coming from the top 10 pharmaceutical companies alone.

Australia's strong reputation can enable companies to attract greater investment from large pharmaceuticals companies. With a globally competitive R&D tax incentive scheme and clinical trial cost containments through initiatives like cost standardisations, Australia can strengthen its position as an attractive and world-class destination for life sciences and biotech companies to conduct research, clinical trials and develop products that enable medical developments which are changing the quality of life for people all over the world.

3. Biotech:

The biotech industry has never been more exciting and is making significant developments in healthcare. Traditional pharmaceuticals are investing heavily in biotech and biopharmaceuticals, driving the rise of biopharmaceutical companies, and the maturation of biotech advancements in R&D.

Non-communicable diseases, called 'one of the greatest public health challenges of the 21st century' by the World Health Organisation, will face many worthy biotech opponents in the coming years. The growing market need for treatments for non-communicable diseases due to a substantial rise of occurrences in emerging economies and an ageing population is complemented by the increased interest in early-stage biotech companies (mentioned above). We expect to see a gradual increase in M&A activity in areas like cancer therapy treatments and therapeutic treatment for age-related neurodegenerative diseases.

In Australia, the establishment by the Australian Government of its A$500 million Biomedical Translation Fund (aimed at converting biomedical discoveries to high growth potential companies) will encourage more venture capital-backed biotech companies to emerge. This will also increase the momentum for progress in prominent techniques and treatments being explored involving genomics, gene-editing and genetic engineering, which is a space to watch this year. On the medical tech front, the CRISPR/Cas9 technique was used in a human trial for the first time late last year in China, bringing gene-editing closer to development and commercialisation. Gene-editing and genomics are also being used in agricultural biotech to develop techniques that improve plants, animals and microorganisms. (See more in our *Australian Food and Agribusiness 2017: Key Themes* report.) Industrial biotech looks to reduce reliance on fossil fuels in electricity generation and plastic production, developing biomasses and biofuels as viable commercial replacements. Various regulatory and policy initiatives have also lent their support to these emerging industries, like the Queensland biofuel mandate which commenced this year, supporting growth of the biotech industry.

Case Study

Many venture and seed capital firms are taking advantage of the Biomedical Translation Fund (**BTF**). Examples include:

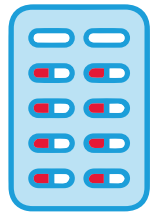
- Brandon Capital Partners established the $230 million Medical Research Commercialisation Fund in 2016 ($115 million from the BTF and $115 million from private investors) to invest in maturing technologies that have progressed to clinical trials *(MinterEllison assisted in establishing this fund)*;
- OneVentures Capital established a similar fund in 2016 ($170 million) that focuses on investments in companies with products that have reached clinical proof-of-concept stage; and
- BioScience Managers established a $100 million fund in 2016 that seeks to invest in Australian biomedical companies to finance their development and commercialisation stages.

In Australia, the establishment by the Australian Government of its A$500 million Biomedical Translation Fund will encourage more venture capital-backed biotech companies to emerge

Three key challenges

1. Pressure on drug prices:

The media has highlighted the controversial nature of drug pricing in recent years, and this continues to affect the industry. As advocates counter the negative publicity around these price increases, world leaders continue to take action to limit drug pricing. Recently, the UK's National Institute for Health and Care Excellence only approved of a certain late-stage cancer drug after an agreement was reached to reduce the price of treatment. The US administration has also made statements about working with pharmaceuticals to lower drug prices.



32% of pharmaceuticals stated 'lower profit margins to remain competitive' as a challenge

In Australia, pharmaceuticals listed on the PBS are subject to regulated price reductions. 32% of pharmaceutical companies surveyed by ABS in 2014 stated 'lower profit margins to remain competitive' as the most significant factor hampering their pharmaceutical and medical technologies businesses. Since then, changes to the PBS has further intensified downward pressure on prices, resulting in price reductions in over 2,000 medicine brands from October 2016 and up to 30% price reductions in over 1,100 medicine brands from 1 April 2017.

2017 will see the pricing impact of biosimilars in Australia. The Federal Government adjusted the pricing consequences of biosimilars recently, effecting a 16% price drop on reference brands upon listing of a biosimilar on the PBS, similar to the treatment of generics. As more biosimilars enter the market, biopharmaceutical revenues will be affected. Notably, pharmaceutical companies are increasingly reluctant to apply for reimbursement via the PBS due to the lengthy process and high risk of an unviable price being set on listing.

Price cuts to expensive medicines are expected to continue for the next five years in Australia. Additionally, global policy targeting price deflations to drug prices will place future strains on the bottom line of affected manufacturers, wholesalers and retailers. In Australia, wholesalers are expected to continue to experience weak revenue gains with the PBS resulting in falling unit prices and lower per-unit margins, despite rising sales measured in volume. However, for M&A activity, falling revenues will result in lower valuations, making it more attractive for large pharmaceutical companies seeking to capitalise on market-driven discounts.

2. Emerging economies:

Emerging economies pose two challenges for the Australian life sciences and biotech industry – access and competition for investment.

Access: The increase in protectionist policies may hinder global trade and investment, which could have adverse impacts on the inflow of investment to Australia and exports of pharmaceutical and biopharmaceutical products overseas.

Many emerging economies, which are fast becoming major markets for the life sciences industry, have adopted protectionist policies that may hinder the penetration and expansion of Australian and other international pharmaceutical and biopharmaceutical companies. Some examples include China, Brazil (Australia's largest pharmaceutical export partner) and Russia's preferential treatment of local generics over off-patent international brands. Companies that are able to access those markets face a myriad of other challenges including uncertainty in and/or a lack of regulatory controls, weak intellectual property protections and establishing the necessary infrastructure cost-effectively.

Global investment: With the life sciences industry shifting towards R&D, manufacturing and distribution of biopharmaceuticals, remaining an attractive biotech location is paramount. Emerging economies are increasingly competitive in attracting investment and talent in biotech. Like Australia, China, South Korea and India are making biotech a top priority. Australia can remain an important part of this sector by looking to identified or suggested areas for improvement, including strengthening its patent and IP protection, increasing the data exclusivity protection term to be similar to that of the US and EU, promoting better R&D environments to drive increased business expenditures in biotech R&D, and provide incentives to retain more talent.

3. Cybersecurity:

Life sciences companies are increasingly susceptible to cyber attacks on valuable IP, digital assets and sensitive medical data. Healthcare companies have constantly been rated as the lowest performers in protecting against cybersecurity risks as many of them rely on out-of-date legacy systems and have only recently started investing in cybersecurity. Of the US healthcare organisations represented in a study by Ponemon late last year, almost 90% had experienced a data breach in the past two years and almost 45% had more than five data breaches over the same period. 88% of all healthcare manufacturers have had malware infections. The pharmaceutical industry fares worse, ranking amongst the lowest performers in cybersecurity. The industry's continued drug pricing controversies also increases its risk of attacks by 'hacktivists'.

Australian healthcare and pharmaceutical organisations are unlikely to buck this trend. Last year, the Royal Melbourne Hospital's computer systems were infected by computer viruses, and Red Cross Australia admitted to a leak of half a million blood donors' personal information in a data breach. Electronic medical devices vulnerable to hacking contribute to the already rampant DDoS attacks, and potentially resulting in dire consequences if its user is medically reliant on its functions.

As the industry becomes increasingly digitised, increased attention must be paid to mitigate cybersecurity risks. (For more on cybersecurity and how to mitigate the risks, see our report *Perspectives on Cyber Risk 2017*).

MinterEllison's Life Sciences and Biotech team has extensive experience in this sector and is well placed to assist you in relation to any queries you may have or matters where you would like assistance

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