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Healthcare 2016 Year in Review - Australia

In our first Healthcare Update for 2017, we provide an overview of developments over the course of the last 12 months in Privacy, Product Liability, Employment, Intellectual Property, Compliance, Corporate, Regulatory, Transparency and Pricing which impact upon the healthcare sector within Australia.



Elisabeth White
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Privacy

Big data

The healthcare industries already make extensive use of data, statistical and quantitative analytics, and explanatory and predictive modelling. Moving forward, one of the key challenges for big data in healthcare will be balancing the need for broad access to data, with the need to protect personal privacy rights and give individuals appropriate control over data collected about them. A lack of consumer confidence, and numerous barriers to sharing and releasing health data, are currently stymieing the use and value of Australia's data, to the detriment of public health and businesses alike.

To address some of these concerns, the Office of the Australian Information Commissioner (OAIC) released a consultation draft Guide to big data and the Australian Privacy Principles (Guide) in May 2016. In releasing this Guide, the OAIC intended to assist entities to understand how the APPs apply to big data that contains personal information.

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Product Liability

Australian Consumer Law review

The Australian Consumer Law (ACL) commenced on 1 January 2011 and is currently being reviewed by Consumer Affairs Australia and New Zealand (CAANZ).

CAANZ is considering the effectiveness of the ACL, including its product safety provisions, and the administrative and regulatory framework that administers them. CAANZ is also considering whether the law is flexible enough to address various new and emerging issues, such as online shopping. All of these issues have relevance in the healthcare sector.

In addition to public consultation, CAANZ has commissioned an independent assessment of the opportunities to improve the 'multiple regulator' model.

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Employment

There have been a range of significant developments in employment law that will impact upon the healthcare industries, including:

- increases to minimum wages;
- annual leave changes to modern awards;
- the launch of the Fair Work Ombudsman (FWO) 'Anonymous Report' Function;
- significant workplace health and safety (WHS) convictions and prosecutions for employer companies, directors and employees;
- a first WHS conviction for failing to consult;
- formation of the Migrant Workers Taskforce;
- penalty risks for unpaid internships;
- increased focus on accessorial liability by regulator.

Increases to minimum wages

The Fair Work Commission's Panel for annual wage reviews released its Annual Wage Review decision on 31 May 2016. This decision, effective 1 July 2016, increased minimum award wages across the board by 2.4%. As a result, the weekly minimum wage has increased from \$656.90 to \$672.70 (increase of \$15.80) and the hourly minimum wage has increased from \$17.29 to \$17.70 (increase of 41 cents).

Annual leave changes to modern awards

Taking effect from 29 July 2016, most modern awards have been varied to incorporate changes to the way annual leave is managed and paid.

Launch of FWO 'Anonymous Report' Function

May 2016 saw the launch of the Anonymous Report function on the Fair Work Ombudsman (FWO) website. This allows employees to make reports about employers, and employers to report on other businesses, when concerned about unlawful behaviour but unwilling to be directly involved in a complaint. This action has been taken in response to community demand for such a service, and has already received a substantial number of 'tip-offs', largely about wage rates thus far.

Significant WHS convictions and prosecutions for employer companies, directors and employees

Momentum for prosecutions and penalties under various state based workplace health and safety (WHS) legislation is growing, as shown by a number of recent convictions with substantial fines ordered.

First WHS conviction for failing to consult

The South Australian Industrial Relations Court has recorded the first conviction against a company for failing to comply with the duty to consult, cooperate and coordinate activities with other duty holders in relation to workplace health and safety matters. In this case, a trainee and apprentice placement organisation placed an apprentice in a position with a roofing company. The apprentice suffered 'horrific injuries' as a result of a workplace incident. The failure of the placement organisation to engage in a consultation process with the roofing company about its WHS policies and procedures resulted in a \$12,000 fine (a fraction of the potential maximum penalty of \$100,000 for a corporation).

Migrant Workers Taskforce

The Migrant Workers Taskforce, lead by Professor Allan Fels, has been formed to consult the Coalition on policies to improve employment protections for overseas workers. This action is part of the efforts to 'crack down' on employers who take advantage of vulnerable migrant workers through underpayments and other contraventions of Australia's employment standards. The Taskforce will assess the issue in a range of industries, with a focus on use of short-term, short-stay visa contract labour.

Penalty risks for unpaid internships

The FWO has continued its focus on unlawful unpaid internship schemes. In June 2016, the Federal Circuit Court issued a fine of over \$270,000 to AIMG BQ, an Australian-based Chinese language media agency, for exploiting a student who worked as an 'intern' for 180 hours over a period of four months, unpaid. The Federal Court found that it was unlawful for the internship to be unpaid because it was not a formal part of the student's studies.

Increased focus on accessorial liability by regulator

Section 550 of the Fair Work Act 2009 (Cth) allows persons involved in a contravention of a civil remedy provision to be held liable for the contravention in addition to, or instead of, the employer business. In July 2016 the Office of the FWO confirmed that this provision has been increasingly used to penalise and recover compensation for the mistreatment of employees.

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Intellectual Property

Will the real exclusive licensee please stand up?

Exclusive patent licences in Australia should be reviewed in view of Federal Court decisions, which consider whether Australian licensees have standing to commence proceedings for patent infringement.

Patent litigation round-up

Once again, no shortage of patent litigation in Australia involving the healthcare industries in 2016. We provide snap shots of key developments from the following cases:

- [Les Laboratoires Servier v Apotex Pty Ltd](#) [2016] FCAFC 27
- [GlaxoSmithKline Consumer Healthcare Investments \(Ireland\) \(No.2\) Limited v Apotex Pty Ltd](#) [2016] FCA 608
- [GlaxoSmithKline Australia Pty Ltd v Reckitt Benckiser Healthcare \(UK\) Ltd](#) [2016] FCAFC 90

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Compliance

A range of corporate compliance developments in 2016 have broad application to Australian corporations, including those within the healthcare industries.

Amendments to Australia's anti-bribery and corruption laws

In February 2016, Australia introduced false accounting offences to its *Criminal Code 1995* (Cth) to comply with the *OECD Anti-Bribery Convention* provisions on the falsification of books and records. The offences, relating to intentional or reckless false dealing with accounting documents which facilitates, conceals or disguises the receipt or provision of a benefit to another person that are not legitimately due, carry hefty penalties.

Senate inquiry into foreign bribery relaunched

On 24 June 2016, the Senate referred an inquiry to the Senate Economics References Committee for foreign bribery. The inquiry was due to be reported by 1 July 2016 but it lapsed with the federal election on 2 July 2016.

Proposed Commonwealth deferred prosecution agreement scheme

The federal government is also considering whether to enable prosecutors to enter into deferred prosecution agreements (DPAs) with corporations which self-report wrongdoing. The proposal for DPAs was first raised in a consultation paper in March 2016 after ministerial meetings at the Organisation for Economic Co-operation and Development (OECD). This follows the introduction of DPAs in the UK, and the constant use of DPAs in the US in response to corruption allegations.

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Corporate

M&A Healthcare deals

According to Thomson Reuters, the total value of announced M&A transactions was US\$3.7 trillion during 2016, a 16% decrease from record highs reached during 2015.

Brexit and Healthcare

On 23 June 2016, a referendum was passed in the UK to "Brexit" or exit the EU. Brexit has brought with it significant uncertainty regarding the terms of the future relationship between the UK, the EU and the companies in all sectors, including the healthcare sector, which trade in and with them.

Healthcare and the Australian Federal Government election

Healthcare emerged as a key election issue in the Australian federal election which was held on 2 July 2016.

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Regulatory, Transparency and Pricing

Medicines and medical devices reform

In September 2016 the Australian Federal Government released its response to an expert panel report on Medicines and Medical Device Regulation (available [here](#)). The Government, on the whole, accepted the 58 recommendations for reform.

The expert panel was convened to undertake a review and benchmark Therapeutic Goods Administration (TGA) regulatory requirements against international authorities, to ensure there is an appropriate balance between risk and benefit in the regulation of prescription, over-the-counter, complementary medicines and medical devices and to simplify and streamline the approval processes undertaken by the TGA.

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Medicines Australia Code - full transparency measures now in effect

The Medicines Australia Code of Conduct sets out the minimum standards required to promote prescription products in Australia for Medicines Australia member companies.

The 18th edition of the Code came into effect in May 2015, introducing significant changes including additional transparency measures around payments and other financial relationships between pharmaceutical companies and healthcare professionals (HCPs). In October 2016, these transparency measures were implemented in full.

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Pricing

We provide a snap shot of some key pricing developments and controversies in 2016.

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New medicine labelling standards


In August 2016, a new Therapeutic Goods Order was issued implementing a range of changes including:

- the location of the active ingredient on the packaging label
- standardised Critical Health Information (CHI) in table form
- more information about non-active ingredients which may cause allergic reactions
- more room for dispensing labels on prescription medicines

The previous order was more than 16 years old and did not align with labelling standards set by overseas regulators.

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