In Practice

Healthy growth

Lawyers in the healthcare and pharmaceutical sectors need to keep abreast of rapid technological developments, regulatory changes and consumer demands, writes **Tom Lodewyke**

THE HEALTHCARE and pharmaceutical space is a scientific hotbed, with advances in areas such as genomics, stem cell therapy and vaccination driving change on both business and regulatory levels.

While this keeps all legal practitioners in this field on their toes, there is no 'typical' healthcare and pharmaceutical lawyer. They practise across diverse sectors of the health industry and many different types of law.

Three of the major divisions, particularly in Australia, are aged care, pharmaceuticals and intellectual property.

Growing demand

Aged care is an important sector for many firms that practise healthcare law, especially considering Australia's ageing population. This includes advising companies that own and operate nursing homes and other aged care facilities, as well as home care providers.

Alison Choy Flannigan, a partner in the healthcare practice at Holman Webb, says aged care is a key growth area in the health sector.

"Australia has an ageing population, and … the government has moved towards what we call consumer-directed care," she says.

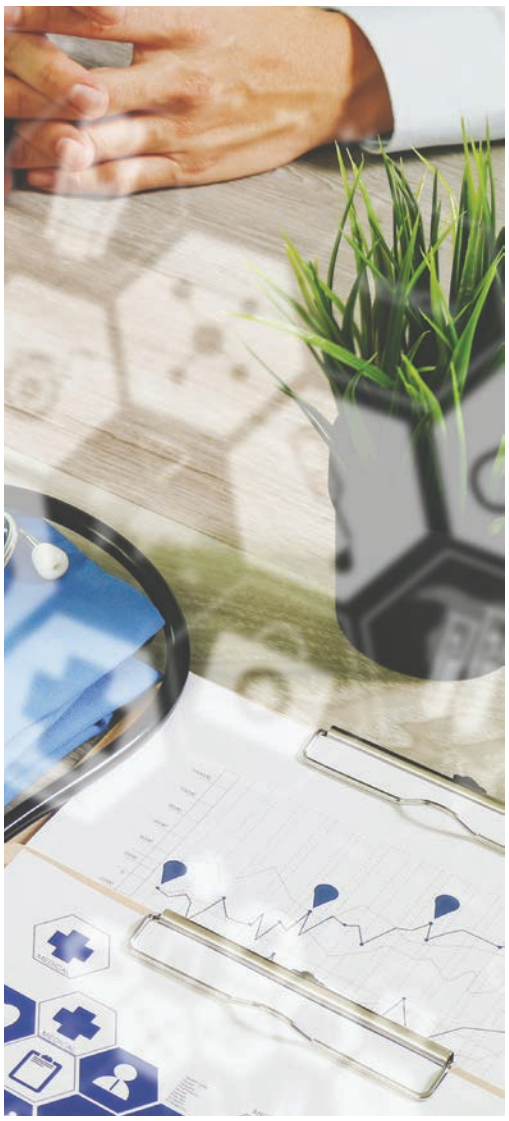
"Home care packages were previously allocated via grant rounds, and from February 2017 in home care it's been opened up to the market, so now the consumer can choose.

"So we've seen an influx of new entrants into the home care industry, and that's created a lot more competition in the market and market disruption."

Ms Choy Flannigan adds that while there is a lot of work in aged care, it is a sector where expert knowledge is required to deliver great client outcomes.

"There's been a lot more firms interested in aged care, but there are only a number of firms that truly have expertise in the area," she says.

"It's very highly regulated, so you



do really need to understand the legislation to properly advise clients in this area. It's not just commercial law, it's also understanding the legislation, understanding the industry and how it works – what's practical, what's not practical."

Ben McLaughlin, the chair of Baker McKenzie's global healthcare industry group, says a significant development in the not-too-distant future will be the emergence of long-distance delivery of medical services directly to people's homes.

"Say my elderly parents in Queensland, they won't have to go and wait at a hospital to see a specialist," he says.

"Instead they'll stay at home and when the time for the appointment comes, they'll just dial up someone on a TV screen or some sort of screen, and they can be diagnosed over the phone.

"Perhaps a nurse will attend to them in their home and they can connect to some kind of machine which can provide information to the specialist, no matter where she's located: she could be in Brisbane or Sydney, or elsewhere overseas. And that's really important for rural Australia, and it's [also] important for Asia."

The cutting edge

Technological developments are also driving change in the pharmaceutical sector, according to Bird & Bird intellectual property partner Lynne Lewis.

Ms Lewis specialises in pharmaceutical and biotech law, among other areas, and says the emergence of biologics is one of the most significant changes facing pharmaceutical lawyers in Australia.

'Biologics' refers to products that are made using living systems, such as microorganisms, as opposed to being synthesised. This can make their exact composition hard to determine, posing regulatory challenges.

"At the moment, I think the biggest issue is grappling with particularly how biologics are going to be treated by the TGA [Therapeutic Goods Administration], how they're going to be treated in the context of PBS [Pharmaceutical Benefits Scheme], and the changing shape of the market brought about by biologics," says Ms Lewis.

She adds that the reprocessing of medical devices is another trend that could bring about regulatory change. At present, she says, only Germany allows companies to reprocess and sell single-use medical devices, though there is growing interest in this practice in Australia.

"I know of some offshore companies that are looking at Australia as a potential market to come here to collect, from hospitals predominantly, used devices and reprocess them, potentially either onshore or offshore, and resupply them in Australia," Ms Lewis says.

"This would increase competition by allowing new companies to enter the market and resell medical devices in a 'generic' form", she says.

"That will raise all sorts of issues, from patent law through to whether our TGA will actually even allow it."

A global industry

International work is prominent in the healthcare and pharmaceutical sectors. Rob McInnes, an intellectual property partner at DibbsBarker specialising in life sciences and healthcare, says the legal differences between jurisdictions pose additional challenges.

"Just about all of my transactions are cross-border," Mr McInnes says.

"You've got to have a working understanding of not just the foreign laws that impact the contracts that you're working on, but also of the foreign ways of doing business.

"A big challenge is licensing into China, because China has technology import-export regulations that essentially override a lot of the causes in licence agreements that an Australian company would see as completely normal and even mandatory or necessary."

Mr McInnes notes that many of the companies he acts for are developing more complex relationships with their Chinese suppliers.

"We've moved from just doing very simple contract manufacturing in China where the Chinese manufacturer purely does what it's told to a more co-development relationship with the Chinese supplier," he says.

"The issue there is that what used to be a simple manufacturing agreement is now a collaborative development agreement with intellectual property flowing each way, and so the intellectual property provisions of these agreements are very complex and have to work under both legal systems."

Double threat

Not only does healthcare and pharmaceutical law require a strong understanding of foreign regulations, it also demands specialist knowledge of the science behind clients' businesses. It is for this reason that many lawyers in this area have scientific backgrounds.

Dr Teresa Nicoletti, a partner in Mills Oakley's intellectual property team, previously worked in the pharmaceutical industry as a PhD scientist.

"I was in the medical and regulatory environment and actually did law because I didn't feel the lawyers we engaged had sufficient understanding of the science, and thought that was quite a weakness in the legal industry," she says.

"All of our team are scientists and lawyers, because a lot of the work that we advise on, you do need a good grasp of the technical issues."

Mr McInnes adds, "Simply having the vocabulary and knowing how to think like a researcher and like a scientist makes a massive difference to having an understanding of your clients and what they're about".

"There's no shortage of work and it's highly specialised work, and if you look at the rankings you'll see that there's really only a couple of dozen people who do this kind of work at the highest level."

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> Holman Webb

It is also important for lawyers to have a sound understanding of the commercial side of healthcare. Ms Choy Flannigan previously worked in-house as the general counsel of hospital group Ramsay Health Care, and says this experience informed her current practice by providing a solid understanding of the health business.

"Both being general counsel and private practice have advantages and disadvantages, but certainly I think that my time as general counsel has enabled me to become a commercially astute lawyer, understanding the business priorities as compared to someone who's never been in-house," she says.

Constant change

In a sector as broad as healthcare and pharmaceuticals, there are always a multitude of changes on the horizon. As in every legal practice area, digital technology and big data are generating disruption in healthcare.

"One of our larger clients, which used to focus very much on making a particularly effective device, has now started to focus increasingly on what it does with the data from the devices in the cloud, and it has released an app that shows patients their data from the device and how they're doing," says Mr McInnes.

Ms Choy Flannigan adds that 'personalised medicine' is a significant development in the health space.

"What [researchers] can do is find out more information about patients and tailor the description of the medicines to a particular patient.

"So, for example, they'll find that some medicines work better with some people with certain racial profiles than others, so rather than wasting a lot of money prescribing medications for racial populations that are ineffective, then they can focus it on the right drugs for the right person.

"All these things that are happening in medicine are all about getting a better patient outcome at a reduced cost and less risk."