Life sciences

December 2016

Welcome to our final Life Sciences update of 2016. In this edition we cover Wilkes v DePuy (the recent judgment that deals with medical products liability and is a boost for defendants), the Brexit debate continued, fitness trackers making people unfit and insurers and manufacturers preparing for the outbreak of rare diseases.

A Christmas present for medical device manufacturers – and the public

Wilkes v DePuy[1] handed down by Hickinbottom J on 6 December 2016, is a product liability judgment for medical devices in this highly regulated area. It concerns a claim following the failure of a hip replacement prosthesis. more›

Steps in the wrong direction

Health Secretary Jeremy Hunt has announced plans for data from health apps and wearable activity trackers to be linked directly to patient records. more›

Headline grabbing diseases

In 2015 the public feared Ebola. In 2016 it was Zika. As we prepare to enter 2017, people will hope that no new outbreak of a little heard of disease tests our assumption that medical advances are winning the age old fight against disease. more›

The Brexit Debate continued

As we await the verdict of the Supreme Court on how the Government can trigger Article 50, Brexit has the potential to become the most overused word in the English language, and lose all meaning. more›

Any comments or queries?

Dorothy Flower
Partner
+44 20 3060 6481
dorothy.flower@rpc.co.uk

Peter Rudd-Clarke
Senior Associate
+44 20 3060 6535
peter.rudd-clarke@rpc.co.uk

Emma Kislingbury
Associate
+44 20 3060 6131
emma.kislingbury@rpc.co.uk

Genevieve Isherwood
Associate
+44 20 3060 6213
genevieve.isherwood@rpc.co.uk

A Christmas present for medical device manufacturers – and the public

Wilkes v DePuy[1] handed down by Hickinbottom J on 6 December 2016, is a product liability judgment for medical devices in this highly regulated area. It concerns a claim following the failure of a hip replacement prosthesis. The Claimant contended that a fracture after just three years meant that the device was defective under the Consumer Protection Act 1987 (the Act). A product will be defective under the Act if its safety is not such as persons generally are entitled to expect.

There have been relatively few judgments in nearly 20 years since the Act was passed, and very little in the way of guidance from the courts on the application of the Act in the context of medical devices. The leading judgment, until *Wilkes*, had been a decision from 2001 which did not concern medical devices and, in any case, was handed down before the regulations governing medical products came into force in 2002.

In *Wilkes* Hickinbottom J found that the hip prosthesis was not defective. In doing so, the judge drew a number of conclusions. For manufacturers of medical devices, the part of the judgment that may have the furthest reaching consequences concerns the importance of the regulatory regime to claims brought under the Act.

The court found that compliance with standards and regulations, whilst not providing a complete defence, will be given considerable weight by the courts in determining whether a product meets the expected standard of safety. This is the first judgment under the Act to place this level of importance on regulation when determining whether a product is defective. Medical devices marketed in the European Union are amongst the most highly regulated products in the world. In order to be marketed legally, medical devices must comply with regulations that require manufacturers to submit their design and manufacturing processes to the scrutiny of notified bodies, approved by regulators, before the manufacturer can affix the CE mark and sell them. Manufacturers are obliged to comply with ongoing obligations once the products are on the market.

The point of ever closer regulation and tighter standards is to protect the public, particularly in the context of medical devices. The importance of Hickinbottom J's judgment cannot be underestimated. The judgment recognises that the regulations have been designed to safeguard the public and this is relevant to determining if a product is defective under the Act.

The Act, and the Product Liability Directive, apply a strict liability regime to manufacturers who manufacture or supply defective products. The legislation was enacted long before the 2002 regulations came into effect. This judgment, handed down in the modern era, reflects the current climate in which manufacturers spend considerable time and money in ensuring that their products are compliant and as safe as can be established by laboratory testing before they are brought to the market.

The upsurge in medical devices litigation had caused some to fear that innovation in life sciences would be stifled. It was a concern that the increasing burden of regulations was not accompanied by a decrease in litigation. This judgment may check unmerited litigation where there is evidence that medical devices have been closely scrutinised under the regulatory regime before being placed on the market. This is good news for manufacturers. It is also good news for the public if it leads to a greater range of products brought to the market by responsible manufacturers.

Back to contents>

1. [2016] EWHC 3096 (QB)

Steps in the wrong direction

Health Secretary Jeremy Hunt has announced plans for data from health apps and wearable activity trackers to be linked directly to patient records. These data have potential use for PHI and travel insurers, giving them access to information such as users' activity levels measured by steps taken in a day. The data could be used to set premium rates for private medical cover or assess an individual's risk level for travel insurance.

Data generated by these devices does not always give the full picture. Hitting a daily target for steps taken does not necessarily correlate with a healthy lifestyle.

The findings of a recent study by the University of Pittsburgh suggest that wearable fitness trackers, which continue to grow in popularity and sophistication, may not be the weight loss wonders we have been led to believe.

The Pittsburgh study monitored weight loss among 471 patients to test whether technology-enhanced dieting gives better results than the tech free alternative.

Interestingly, and somewhat surprisingly, at 24 months, the estimated mean weight loss for those participants using the fitness trackers was 3.5kg, whereas, for those sticking to the tech-free diet, it was 5.9kg. Both groups showed improvements in body composition, fitness, physical activity, and diet, with no significant difference between them.

The study concluded that devices that monitor and provide feedback on physical activity may not offer an advantage over standard behavioural weight loss approaches. One theory which has come out of the Pittsburgh study's findings is that constant awareness of one's activity levels leads people to reward themselves with treats when they hit a notional target.

A second recent study, published in The Lancet Diabetes and Endocrinology, tracked 800 people from Singapore to assess whether pedometers improved their health. The results showed that the use of such devices is unlikely to be a panacea for rising rates of chronic disease and, for those participants who did record improved levels of physical activity, the increase was "probably not enough to generate noticeable improvements in any health outcomes".

So where does this leave insurers and manufacturers? Do these devices provide useful data for assessing risks? Should device manufacturers prepare themselves for an angry backlash from consumers who might have mistakenly been led to believe that their wrist strap guaranteed them a slimmer, healthier new life?

For insurers, the point to remember is that no matter how accurate they are, fitness trackers cannot guarantee results – their effectiveness as a tool will inevitably depend on how they are used. Understanding this will have an impact on how much use insurers make of the data generated by these devices, in assessing insureds' lifestyles.

For manufacturers, they should ensure that their customers understand that their devices may help users follow a healthy lifestyle but the devices cannot do the hard work for them. It will improve a user's health to take more steps in a day, unless those steps lead to the biscuit jar. Individuals have the responsibility to decide whether that "well earned" treat is really justified by those extra few steps...

Back to contents>

Headline grabbing diseases

In 2015 the public feared Ebola. In 2016 it was Zika. As we prepare to enter 2017, people will hope that no new outbreak of a little heard of disease tests our assumption that medical advances are winning the age old fight against disease. Taking a step back from the headlines, though, insurers will adopt a more measured approach to assessing the liability risks presented by novel diseases.

When a poorly understood and relatively unknown disease grabs the headlines, some parts of the world may be hit hard and lives devastated. For the rest of the world, the media reaction outweighs the true impact on the population's health. Insurers may be affected if they provide business interruption coverage to companies vulnerable to the sudden spread of a particular disease, such as hotels in an affected region, or companies with supply chains extending to the part of the world where the disease emerges. Insurers may also be affected if they provide liability insurance to manufacturers that produce equipment designed to combat the disease. However, for the most part, insurers will be less worried than the public when a rare disease hits the news.

Studies into public responses around the world reveal disproportionately high levels of panic in populations, where a disease is rare and the outbreak is unexpected. For insurers and their clients, a proportionate response makes more sense. This involves a financial analysis of the impact of the disease, away from the emotional impact. Companies and insurers may want to assess the statistical risk of production levels and supply chains being disrupted, if at all and plan accordingly.

A proportionate response could involve assessing how the risks would affect certain businesses. Healthcare providers should take time to stress-test generic protocols designed to combat rare diseases, before they are required in a hurry. Manufacturers of medical products used against a broad range of diseases should ensure that products are supplied with warnings over the limitations of the equipment, explaining that the equipment has been tested to cater for a limited range of scenarios.

Thankfully, the headline grabbing diseases that have worried the public in recent years have not had the impact that some feared. If 2017 sees the rise of another rare disease, insurers will doubtless take a proportionate approach to assessing the risks.

Back to contents>

The Brexit Debate continued

As we await the verdict of the Supreme Court on how the Government can trigger Article 50, Brexit has the potential to become the most overused word in the English language, and lose all meaning. However, as it appears from Government indications that the UK will not continue to participate in the free movement of labour, it is time to assess the likely impact for the Life Sciences industry of the UK leaving the single market that is part and parcel of free movement within the EU.

Funding

To date Britain has benefited greatly from EU funding for Life Sciences research and development – receiving €8.8bn in grants in 2007-13 (and accessing more funding per capita than any other country in the EU). Whether the UK will remain in this favourable position needs to be considered.

Being a member of the EU provides access to a variety of funding channels, the largest of which is Horizon 2020 (a programme with the capacity to provide €80 billion between 2014 and 2020 to assist public/private sector collaborations). Whilst no longer being part of the EU does not preclude an organisation from receiving such an EU grant it is likely to complicate it. For example, to continue to receive funding from Horizon 2020 an organisation will have to apply to become "associated with Horizon 2020".

Following the referendum, the Department for Business Innovation and Skills (now the Department for Business, Energy & Industrial Strategy) suggested that the result would have "no immediate effect on those applying to or participating in Horizon 2020." However, it did note that the "future of UK access to European research and innovation funding will be a matter for future discussions" indicating that negotiation will be necessary.

It is unlikely that the UK will lose access to the entirety of EU funding currently available. However, organisations will need to be prepared for a more difficult process to access funding, and for the likelihood that any funding they do receive will be reduced (if only in the short term whilst the UK's position is negotiated).

Private funding through equity capital, however, is unlikely to be impacted by Brexit, provided the Life Sciences sector remains an attractive industry for investment.

Clinical Trials

The EU clinical trial regime will be overhauled in October 2018 when the new EU Clinical Trials Regulation (No 536/2014) is expected to come into force. The regulation is intended to streamline and simplify clinical trials across the EU by providing a central application and approval process, and an EU wide database.

If the UK becomes a member of the EEA it will still be able to access the single market and it is therefore likely that it would be allowed access to the central clinical trial application process, procedures and database (although potentially at a cost).

However, in the event the UK remains outside the EEA, any UK Life Sciences organisation that wishes to undertake a clinical trial will need to gain separate national approval and regulation in addition to the central EU system (with the corresponding increased administrative and financial burden this will entail).

In addition, without access to the central EU system, there is a risk that any data garnered from UK clinical trials will be considered ancillary to EU wide data, thereby weakening the UK's standing.

Regulation

The EU currently provides a single framework for regulating and approving Life Sciences products. However, as with clinical trials, the potential impact going forward will depend upon whether the UK remains in the EEA (a matter which is currently up for debate given the Prime Minister's recent comments on the free movement of labour).

If the UK is part of the EEA then it will abide by current EU standards in return for access to the single market. Accordingly, in practical terms, there will be little change for UK organisations.

However, should the UK not remain in the EEA then it will need to decide, in conjunction with the MHRA, which regulations and directives it will continue to apply. This would then mean that, for any global or Europe-wide products, manufacturers would have to comply with two separate regulatory frameworks. As the UK is a significantly smaller market than the rest of Europe it is foreseeable that, for commercial reasons, many organisations may prioritise gaining approval in the wider market rather than the UK. It is a possibility, therefore, that the UK's influence in this sphere will diminish.

The potential for the UK's influence to diminish will only be exacerbated by the likelihood that the European Medicines Association will move its headquarters out of London following Brexit (with a corresponding loss of 890 jobs). This is also likely to have an impact on the MHRA who will need to take on extra employees in order to cope with the added burden.

Back to contents>

About RPC

RPC is a modern, progressive and commercially focused City law firm. We have 79 partners and over 600 employees based in London, Hong Kong, Singapore and Bristol.

"... the client-centred modern City legal services business."

At RPC we put our clients and our people at the heart of what we do:

- **Best Legal Adviser status every year since 2009**
- **Best Legal Employer status every year since 2009**
- **Shortlisted for Law Firm of the Year for two consecutive years**
- **Top 30 Most Innovative Law Firms in Europe**

We have also been shortlisted and won a number of industry awards, including:

- **Winner – Law Firm of the Year – The British Legal Awards 2015**
- **Winner – Competition and Regulatory Team of the Year – The British Legal Awards 2015**
- **Winner – Law Firm of the Year – The Lawyer Awards 2014**
- **Winner – Law Firm of the Year – Halsbury Legal Awards 2014**
- **Winner – Commercial Team of the Year – The British Legal Awards 2014**
- **Winner – Competition Team of the Year – Legal Business Awards 2014**
- **Winner – Best Corporate Social Responsibility Initiative – British Insurance Awards 2014**

Areas of expertise

- Banking
- Commercial
- Commercial Litigation
- Competition
- Construction
- Corporate
- Employment
- Insurance
- Intellectual Property
- Media
- Outsourcing
- Pensions
- Private Equity
- Real Estate
- Regulatory
- Reinsurance
- Tax
- Technology

16765

Tower Bridge House
St Katharine's Way
London E1W 1AA
T +44 20 3060 6000

Temple Circus
Temple Way
Bristol BS1 6LW
T +44 20 3060 6000

11/F Three Exchange Square
8 Connaught Place
Central Hong Kong
T +852 2216 7000

12 Marina Boulevard
#38-04 Marina Bay Financial Centre Tower 3
Singapore 018982
T +65 6422 3000