Life sciences

August 2016

Here is our latest life sciences update. Read on for practical tips on the Insurance Act 2015, the implications of the NHS wading into the debate over diagnostic apps, how Brexit may affect medical regulations and impending litigation over fertility treatment. Some of these topics will be addressed in more detail in our next life sciences seminar on 20 September 2016. To register your interest, please email seminars@rpc.co.uk.

12 August 2016: Question Time

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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

Natalie Drew
Associate
+44 20 3060 6601
natalie.drew@rpc.co.uk

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What does the Act do?

The Act will apply to business insurance contracts entered into on or after 12 August 2016. Under the Act, insureds will need to comply with the new duty of "fair presentation" by carrying out a reasonable search for disclosable materials. But that obligation is offset by provisions in the Act that insureds may fulfil their obligations if they disclose sufficient information to put a prudent insurer on notice that it needs to ask further questions. This means that insurers must now sift through information provided at placement and ask questions at that point. It will be too late to ask questions later, when a claim is made. In the case of any future coverage dispute involving the non-disclosure of a material fact, the underwriter will need to show that he/she acted as a prudent insurer by asking the right questions at placement.

Whether the potential insured is a manufacturer of medical devices or pharmaceutical products, having to hand a set of standard questions could help tease out the nature of the risk.

Your starter for ten

Here are our suggested top ten questions.

1. What is the claims history for the product or related product lines?
2. Have any of the company's products been the subject of litigation?
3. What regulatory oversight is the company subject to and what submissions have been made to obtain regulatory approval?
4. Is the company under investigation by regulators and, if so, what for?
5. What clinical trials did the company carry out for its products, were they independently verified and can insurers see the reports?
6. What internal inspection processes does the company have in place to monitor manufacturing standards?
7. Who audits the company and can insurers see the reports?
8. What sort of record keeping does the company have in place to deal with complaints?
9. How does the company monitor industry-wide risks?
10. What reports dealing with industry risks have been considered by management and can insurers see them?

What next?

Questions like this will be the jumping off point for making further enquiries. Given the new obligations on insurers, it will be important to consider the information that comes back and to ask follow up questions until they are satisfied that those enquiries have been answered. Lists of standard questions should be kept under review and updated based on experience.

The value of obtaining detailed information from insureds will be apparent at the beginning of the policy period. Insurers will be furnished with information to support negotiations over coverage terms, as well as explain the level of premium charged. Hopefully, insurers will find

that the underwriting process goes more smoothly if careful questions lead to comprehensive answers from insureds, so limiting the risk of angry heckles from any of the parties involved.

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The word on the political grapevine is that the UK is unlikely to opt for something akin to EEA membership – a 'Norway' style arrangement most similar to the UK's current relationship with the EU. Instead, the Government appears prepared to start redefining the UK's future with a blank sheet of paper. This throws into uncertainty the regulatory landscape for life sciences manufacturers: they may no longer be subject to EU directives and regulations.

The following are three areas that life sciences insurers will want to keep under review as Brexit takes shape.

- **Medicine and medical devices regulations.** The EU regulations determine what counts as a medicine or medical device, how they are regulated and what manufacturers must do to demonstrate and maintain regulatory compliance. Classification according to the EU's sliding scale of 'low' to 'high' risk, detailed submissions to regulators and audits by notified bodies against regulatory standards mean that underwriters currently get a good sense of what they are underwriting. Insurers should be concerned if these regulations are replaced with a regime that is less onerous. An economic downturn could lead to calls by industry to do away with "red tape" to boost manufacturing. If that looks likely, insurers should consider intensifying their own scrutiny of medical products, so that they can fully understand the nature of the risk.
- **Consumer protection legislation.** For insureds and claims handlers, there is uncertainty over the application of consumer protection legislation. Much life sciences litigation is driven by the Consumer Protection Act 1987, which implements the EU's "strict liability" regime derived from the Product Liability Directive. In addition, EU directives impose strict obligations on the UK to meet certain standards, including those in relation to product safety and product recall. This has all led to a familiarity, amongst both claimants and defendants, with almost thirty years of statutory law, peppered with decisions at the national and EU level over the years. At the moment, it seems unlikely that the UK Government will depart significantly from the pro-consumer stance which currently prevails – much of the recent Consumer Rights Act 2015 was UK conceived and it seems likely that the UK will continue in this vein. However, a downturn could prompt manufacturers to argue that consumer law should be recalibrated to be more in manufacturers' favour. If the current consumer protection framework is significantly amended, then claims handlers will find it more difficult to predict the outcome of litigation and set the appropriate reserves.
- **Globalisation: it may come to the rescue.** At present, amid the uncertainty of the impact of Brexit, there is one element in the mix that may trump (no pun intended) all others and so smooth out the path ahead. UK based manufacturers will want to manufacture goods that can be marketed easily overseas. There is no reason why a device designed and manufactured here cannot be a market leader around the world. Why develop an innovative product that could be useful for the world's population of seven billion but make

it compliant with only the laws of the UK and its population of 65 million? Much life sciences market practice is already based on global standards for this reason. And so perhaps the best approach life sciences insurers can take with their clients is to encourage them to take the opportunity afforded by Brexit to look beyond just UK or EU regulations and embrace global standards, whether set by Europe, the United States or any other economy with a stringent regulator. Amidst the uncertainty and gloom following the referendum, adopting this approach could strike a rare positive note over Brexit.

Now, that would be unusual.

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Clinics, consent and cash

The impending litigation brought by a widow seeking to prevent her frozen embryos from being destroyed brings to light the issue of consent and the storage of embryos. These are extremely sensitive and complex matters which must be considered carefully by clinics, their insurers and lawyers in order to protect patients and to mitigate against the risk of similar litigation.

Samantha Jefferies and her husband, Clive, were undergoing fertility treatment when Clive died suddenly from a brain haemorrhage in 2014; his written consent to the storage of the embryos has since expired.

Like gametes (sperm and eggs), embryos can be stored, as a matter of law, for a maximum of 10 years before written consent must be renewed. In this case, Samantha and Clive had ticked the box to grant consent for the 10 year period. However, they changed this to two years at the request of their clinic (Sussex Downs Fertility Centre) to match the limit of their NHS funding.

Samantha has now launched an action in the High Court to prevent the remaining three frozen embryos from being destroyed.

In the life sciences sector, claims are increasingly brought on the basis of complaints over consent and storage. It is important for clinics, their insurers and their patients, to ensure that such issues are discussed openly and properly, and that the time limit for the expiry of consent is not automatically limited to NHS funding. As a spokesperson for the Human Fertilisation and Embryology Authority (HFEA) commented: "We have made it clear to all clinics that they must not align the storage period a patient consents to, with their payment arrangements".

Despite the HFEA's comments, and a number of previous legal battles by women in similar positions, Samantha Jefferies' legal action to prevent the embryos being destroyed shows that there remain grey areas to the regulations. Clinics and their insurers will be monitoring a case that could have wide-reaching ethical and regulatory implications.

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Mobile health; the NHS grabs it with both hands

Mobile health (mHealth) apps have long been heralded as having the potential to revolutionise the way in which healthcare is accessed. Until recently, the phenomenon of self-diagnosis through smart-phones was considered to be more a risk for the future than for the here and now. However, with the chief executive of NHS England stating this summer that smartphones are one of the "most powerful diagnostic tools now available", we are now on the cusp of an age

of wide-spread self-diagnosis via apps. Insurers need to work with manufacturers to ensure that risks, both from a consumer misuse and data protection standpoint, remain minimal.

The smart

The NHS plans to approve and fund dozens of innovative apps. Those already on the market range from the fairly simple fitness-tracking variety, to those providing more sophisticated diagnostics and treatment options. A quick search in the AppStore throws up a host of cheap and easy-to-access options to download straight onto your phone or tablet.

These apps not only allow users greater access to healthcare, especially in areas where such access is difficult, but also claim to assist diagnose and track diseases, provide more up-to-date public health information and expand access to healthcare training. The NHS is attracted to the potential for them to help improve the health of the population, lower healthcare costs and improve the patient experience generally.

The not so smart

However, as with many advances in the life sciences industry, this development comes with multiple risks attached. The speed of the development of mHealth means that there is necessarily a limit on the long-term data to prove their benefit. There is a chance that users may operate the app incorrectly, input the wrong data, or interpret the advice given more loosely than they would advice from their GP. These factors have the potential to damage the health of users, who in turn could seek redress from manufacturers or suppliers.

There is also a risk of data protection violations with regard to mHealth apps. Users will enter personal data into these apps, including sensitive information about their health, usually protected by patient-doctor confidentiality. The risk with mHealth apps is that they can be easily hacked (a simple password is unlikely to prevent a data breach). Smartphones and tablets have long been an easy target for hackers, containing not only sensitive personal information about the user, but also their financial details.

Insurers will need to recognise the risks by ensuring that their insureds evaluate the likelihood and impact of a data breach and ensure that protocols for notifying individuals, obtaining consent and transferring data have been observed.

Smart insurers

The sophistication of apps, and the potential use to which they can be put, is undergoing rapid change. The NHS's intervention may accelerate the acceptance of apps as diagnostic tools in the hands of users.

Given the pace of developments in mHealth, there is a need for constant post-market surveillance to build up a picture of the biggest risk areas for manufacturers and their insurers.

When assessing a risk, insurers would be advised to pay close attention to the regulatory regime. The MHRA requires manufacturers to implement an effective surveillance system, to capture any recurring misuse of an app, or other frequently-occurring risks. The MHRA recommends the implementation of a registration or activation system that may help trace devices that have been distributed by third parties. These are smart practices that insurers should insist are adhered to, or they may find that they are risking their own financial health.

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16420

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