JLT Specialty Limited provides insurance broking, risk management and claims consulting services to large and international companies. Our success comes from focusing on sectors where we know we can make the greatest difference – using insight, intelligence and imagination to provide expert advice and robust - often unique - solutions. We build partner teams to work side-by-side with you, our network and the market to deliver responses which are carefully considered from all angles.

For more than a decade we have been the world's foremost liability broker for larger life science companies, working with the majority of the leading players in the sector, from pharmaceutical and agricultural to chemical and research institutes.

CONCLUSION

Emerging technology and use of applications introduces new and/or increased risks and opportunities.

Many liabilities can of course be covered by insurance but one does need to determine where the cover could be provided – is it product recall, professional liability or product liability? Is a separate cyber liability cover required?

Much will depend on the definitions and exclusions operating in the various policy forms. For product liability cover, for example, one would need to ensure that the definitions used such as 'Insured's Products', 'Occurrence' and 'Bodily Injury'[7] worked together and, importantly, encompassed services. Not all insurers will be comfortable to provide such cover so in some circumstances it is possible that a separate professional liability policy or limit will need to be procured. Again one would need to ensure the coverage dovetailed with the product liability cover since many professional liability policies will refer to advice/ services given within a certain physical setting.

Good quality advice from your insurance partners who can help with risk identification and tailor insurance language and cover to meet exposures can be crucial.

7 Or other similar and/or interchangeable definitions depending on the policy form

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MEDICAL DEVICES

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Applications as medical devices and their impact on liabilities

With the advancement of technology alongside increased consumer access, many life science companies are increasingly moving towards providing applications on computer, tablet and mobile devices. The variety of these is wide and brings new opportunities and associated risk.

Before looking at some of these risks it is worth pointing out that many of these applications fall under the watch of local regulators. This ensures that certain criteria need to be met pre and post launch. These are mainly focused on patient safety but also mean certain activities may need to be carried out by the application owner.

According to definitions provided by regulators, such as the European Medicines Agency (EMA) and the Food & Drug Administration (FDA), a large number of these applications can be described as medical devices and will be regulated in the same way.

EMA DEVICE DEFINITION

"Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,

intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;" …"In deciding whether a product falls under the MDD[1], particular account shall be taken of the principal mode of action of the product."

FDA[2] DEVICE DEFINITION

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

From these definitions and the consistent appearance of the words 'diagnosis' and 'treatment' one can speculate how easy it is for an application to fall under the auspices of regulators as a medical device.

According to some studies, 31% of cell phone owners, and 52% of smartphone owners, have used their phone to look up health

This introduces regulatory oversight and looks to ensure patient safety. These regulators will have the power or influence to ensure on-going patient safety, including product recalls, re-labelling etc.

EMERGING RISKS

- Incorrect Diagnosis/Treatment - Consider an application that diagnosed the presence of diabetes, for example, or how much insulin was required by a diabetic - this could be deemed a medical device. Applications as medical devices leads to an obvious risk worth stating - should the application recommend an incorrect amount of insulin to be taken, which in turn results in bodily injury, then this could lead to a liability. The pace at which medical science evolves and our understanding of the human body further complicates the above issue. As such continual software updates to applications may need to be applied in order to ensure that the best and most recent diagnostic matrixes are being utilised in order for the devices to provide correct information.
- Applications which link to a patient's pacemaker are already available. The extent that these applications may regulate or dictate the pace at which the heart pumps in the future, rather than an implantable device, will be watched with interest. This will present a number of risks and benefits. If it is learnt that the best pace for a heart to pump at is one beat per minute quicker than we had previously believed then the application can be an effective and helpful tool. However should the application be incorrectly programmed or even hacked into[3] then there is the obvious potential for multi-patient injury. Even Dick Cheney had his wireless function on his defibrillator disabled to avoid such a scenario![4]
- Removal of Learned Intermediary - patients using such applications may be increasingly tempted to remove a physician from any diagnosis/ dosing especially as access to and sophistication of applications increases. According to some studies, 31% of cell phone owners, and 52% of smartphone owners, have used

1 Medical Devices Directive 93/42/EEC

2 Also refer to: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm?utm_source=twitterfeed&utm_medium=twitter

3 http://www.economist.com/blogs/economist-explains/2013/06/economist-explains-5

4 http://www.bbc.co.uk/news/technology-24608435

their phone to look up health or medical information and 19% of smartphone owners have downloaded an application specifically to track or manage health[5]. Currently devices do not acknowledge the presence and effect of other products within the human body. Any reaction between two drugs, for example, which occurs within the body, is outside the control of an application on a phone or tablet. Ensuring the end user is aware of this is critical.

- Data Protection - applications which hold personally identifiable patient data will introduce data protection risks. Differing legislative requirements on data protection exist across numerous countries and all of these will need to be adhered to.
- Cyber Liability - the hacking element mentioned above leads to an interesting emerging risk of cyber liability[6]. Should malware or any other computer nasty be uploaded onto an application, or perhaps more worryingly hidden in the next application update, there are a number of potentially harmful outcomes, worst of all those that could result in bodily injury or damage to end users and or loss of patient data. Robust network safety is a must.
- New Types of Product Recall – a recall of an application may be very different from a recall of a physical product. If an application is defined as a device then they will fall under the auspices of local regulators and recalls will need to be done to certain criteria and guidelines, albeit often referred to as 'voluntary'. Ensuring the necessary process and/or safeguards are in place to be able to recall or 'upgrade' the product will be critical. Releasing an email to update a user may not be sufficient - think how many people do you know who put off updating their software immediately, press the snooze/ remind me in three days button? An alternative which also instructs the patient to see their doctor immediately may be required.

5 http://www.pewinternet.org/2012/11/08/mobile-health-2012/

6 See JLT Life Science's December 2012 bulletin – "Cyber risks in the life science industry"