Product liability and life sciences - trends report

January 2020

As innovation and new technologies are rapidly transforming the way we live, it is imperative that businesses in all industries remain alive to the risks arising from these advancements.

In a life sciences context, healthcare innovation, including smart medical devices, remain at the core of such advancements with the inevitable ongoing associated cyber-security risks. More widely, new technologies, such as autonomous vehicles, are exerting their forces on businesses, and with their benefits come as yet unanswered questions around product liability risk. As technology matures, industry and public bodies alike must adapt their models, processes and positioning to keep apace in this brave new world.

We now of course find ourselves in a more certain political setting than has been the case over the past three years, albeit one that remains highly charged, with the initial stages of Brexit being only a matter of days away. Businesses will be keeping a watchful eye on the status of the Withdrawal Agreement and the extent to which a no deal outcome remains a possibility. Life sciences stakeholders in particular can take comfort from Boris Johnson's post-election Queen's Speech – dominated by Brexit-related legislation including the Medicines and Medical Devices Bill - which upholds the government's strategy of promoting the growth of the UK's life sciences sector.

Kennedys

Looking across the litigation landscape, a rise in mass tort actions such as the Volkswagen and PIP breast implant litigation has fuelled a drive by the European Commission to implement a standardised collective action mechanism across Member States designed to promote access to justice for citizens and companies but without the perceived excesses of US style class actions.

With the EU Commission's collective action agenda now picking up pace after a slow start and a proposed EU Directive for Representative Actions likely to come into force after the Brexit transition period, this key legislative change is expected to lead to an increase in the number of consumers seeking collective redress. As most businesses now operate online and there is an increased reliance upon data-driven technologies, it will soon be easier for consumers to bring cross-border class actions against companies in the event of a worldwide data breach.

Against this backdrop, we consider the key trends in the life science and product liability sectors.

Smart medical devices - where risks falls

The worldwide market for connected/smart medical devices (stationary, implanted and wearable external medical devices) is predicted to grow to US$52.2 billion in 2022. Medical devices using a wireless connection such as pacemakers, defibrillators and monitors are all at risk of exploitation by hackers. Product liability claims may be made where a software vulnerability and/or cyber security risks results in property damage and/or personal injury and is not as safe "as persons are generally entitled to expect".

The risks of these products may fall on potential multiple defendants from the delivery and supply chain (designer, manufacturer, shipper, seller) as well as the treating physician and/or hospital or GP practice, which recommends the smart medical device to the patient. However, smart medical device manufacturers should be mindful that insurance policies may not provide coverage for every consequence of a cyber-attack. They could be left facing substantial costs in defending related product liability claims, and also irreversible reputational damage.

Autonomous vehicles

Currently, if there is a motor accident, liability will lie with the driver of the vehicle if it can be proven that the driver was negligent. However, where an accident occurs as a result of a fully autonomous vehicle and with no human error involved, it follows that liability will shift from driver to manufacturer, who will have responsibility for programming the software and producing the vehicle.

However, for as long as humans actually sit in autonomous vehicles, causation will remain a live issue – the driver or the vehicle? This shift in liability could affect many companies in the manufacturing supply chain including software developers, software providers and telecoms service providers. Each company and their insurer will need to be aware of their potential exposure to liability claims during the transition towards fully autonomous vehicles.

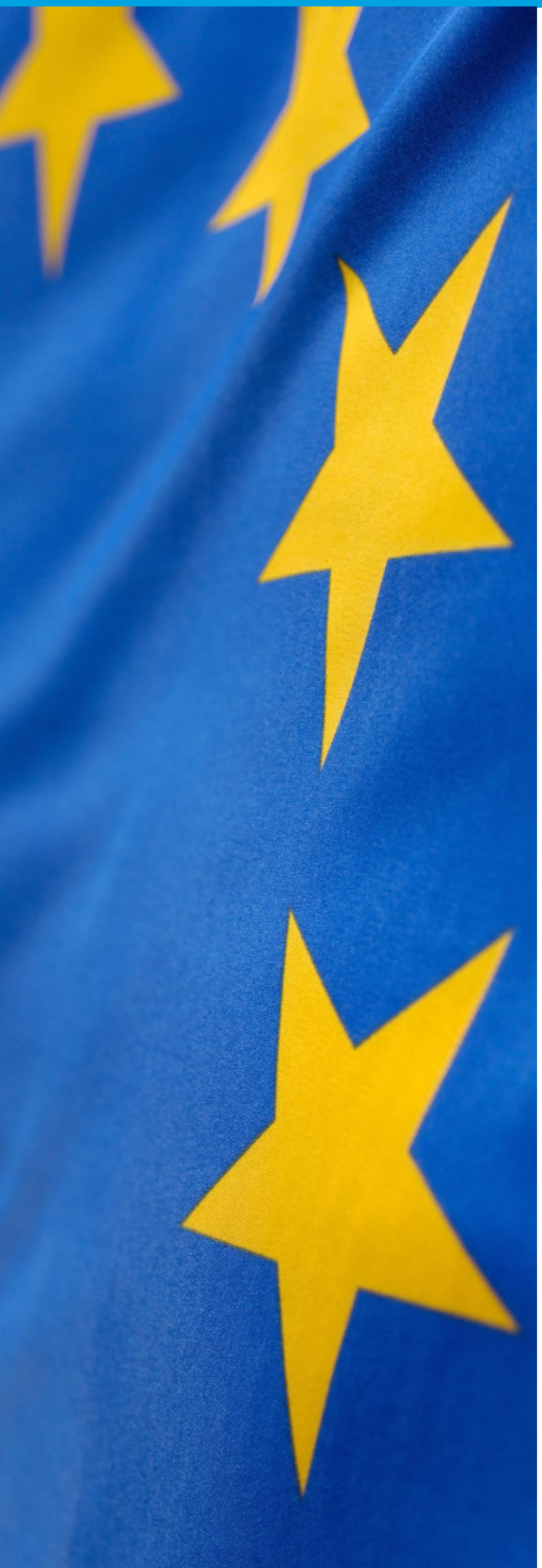
Vaping

The potential risks for users associated with vaping are still emerging. Regulation and research is key to providing certainty to insurers surrounding the long term risks associated with them. Insurers and manufacturers of vape devices should keep up-to-date with the risks and regulations in this area, including the potential long term implications for users and provide suitable warnings, as appropriate.

Nanotechnology

Nanotechnology is a key emerging sector with wide ranging applications in product manufacturing and life sciences. Significant annual growth is expected over the next few years. The EU has named it as one of six key enabling technologies proving that it is now a policy priority for Member States. The US Food and Drug Administration is also engaging: it published an approach to regulation document in 2018 highlighting the need for product specific assessments.

Overall, the expectations are high and mainly focus on patient benefits in the long term (e.g. less scarring, improved drug delivery, targeted treatment). However, some members of the medical community feel that more research and testing are needed to understand and evaluate the risks and safety of this technology. Further, the practical and legal implications are not yet fully known whilst



questions also arise as to technical and economic feasibility. It is likely we will see ongoing development in many spheres although the pace of change may not be as fast as that with other technologies.

Brexit

A Brexit deal has now been agreed in principle and, assuming the European Parliament consents, the UK will formally leave the EU on 31 January with a transition period until 31 December 2020. Despite some uncertainty remaining, there is optimism.

According to the Association of British Pharmaceutical Industry "The Prime Minister's Brexit deal includes an important commitment to exploring close cooperation on medicine regulation. Achieving this will be important in prioritising patients and public health as well as the future of the UK life sciences sector."

Even in the event of a no-deal Brexit, the government has shown a firm commitment to the long-term success of the life sciences sector, guaranteeing funding for all successful competitive UK bids to Horizon 2020 submitted before the UK's departure from the EU as well pledging to increase R&D investment of £2.3 billion in 2021/22. The government's recent Medicines and Medical Devices Bill builds upon this continuing commitment to ensure the "growth of UK life sciences sector to ensure we remain at the forefront of the global life sciences industry".

Regulation

2020 was to see the end of the three year transition period following implementation of the Medical Device Regulations (MDR), due to come into effect on 26 May 2020. Seeking to improve patient safety, ensure transparency and traceability of medical devices and adaptability in view of new technologies and scientific progress in the medical devices sector, the MDR imposes clear and detailed rules that will apply uniformly to EU member states.

> "Industry feedback has suggested the need for an extension of the transition period in order to meet the strict requirements imposed by the MDR."

Industry feedback has however suggested the need for an extension of the transition period given the significant further time necessary for the implementation of the extensive practical changes required by various stakeholders in order to meet the strict requirements imposed by the MDR.

The timing and outcome of Brexit may impact upon the application of the Clinical Trials Regulations (EU) No 536/2014 (CTR) in the UK. The CTR's application in Member States is contingent upon the approval of the Clinical Trials Information System (CTIS), a centralised portal and database which will seek to harmonise the assessment and supervision processes for clinical trials in the EU.

If the CTR does not come into force before the end of the Brexit transition period, the UK will remain aligned with parts of EU legislation within its control so researchers conducting clinical trials can plan with greater certainty by ensuring consistency and co-operation with EU processes.

The UK's departure from the EU will however require a negotiated agreement regarding access to the shared central IT portal and participation in the single assessment model.

Reputational

The life science industry has seen increased growth and innovation over the last year, but the risks and challenges in this industry are just as important to recognise. With the rise in smart medical devices and nanotechnology, the sector is experiencing increased exposure to data and cyber breaches.

Therefore an increased focus on data management and governance in this sector is paramount to preserving its reputation amongst the public, patients, physicians and hospitals alike. An example of this is the use of blockchain technology which can assist, for example, with recall management to provide real time responses to protect the sector's reputation and the patient's safety.

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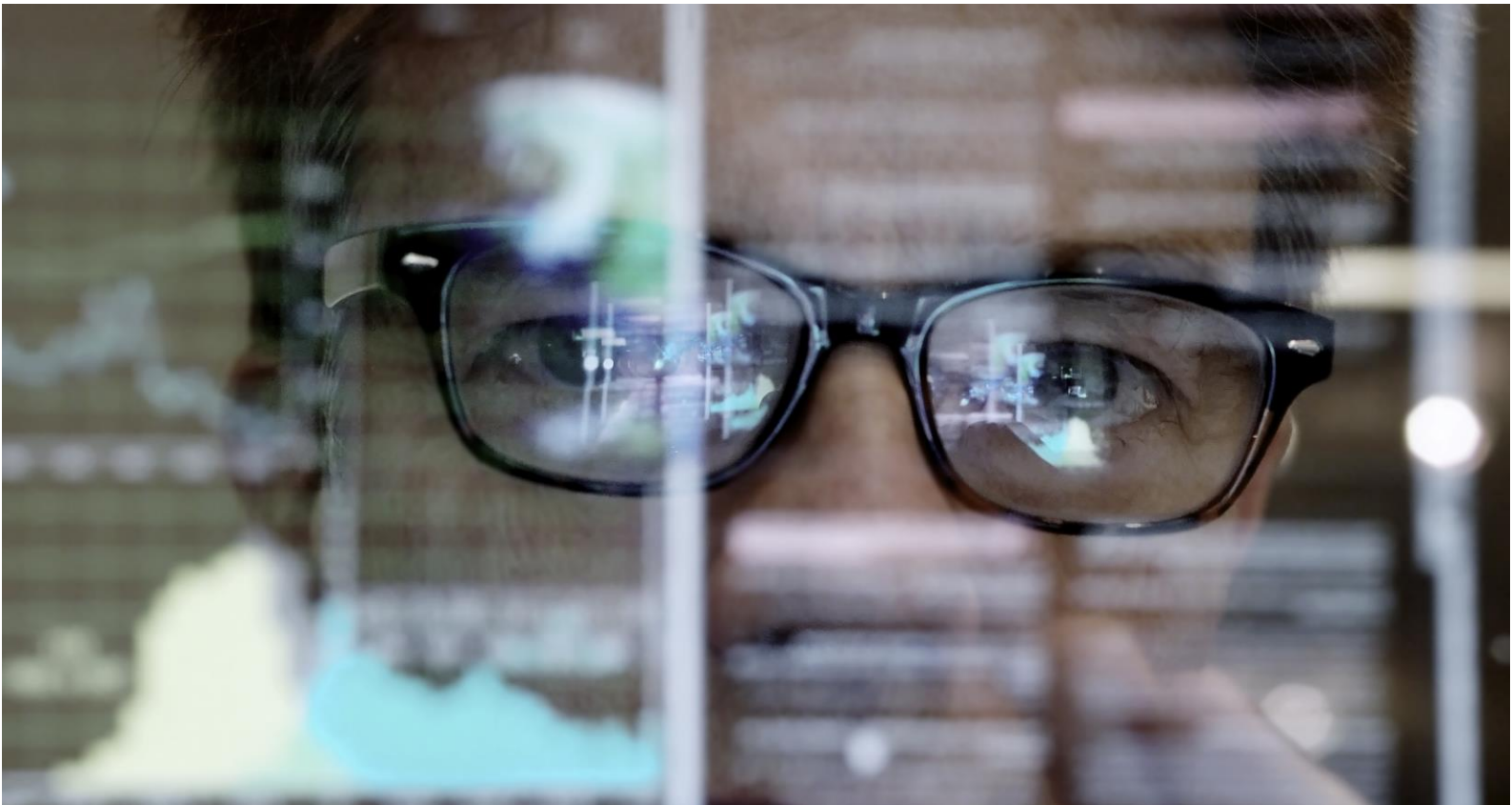
The life science industry must also monitor the external environment for events that could cause reputational damage such as product recalls and group litigation.



Collective redress

The EU has been driving towards the creation and implementation of legislation for collective redress/representative actions by way of a proposed Directive for Representative Actions for some time, and continues its attempts apace.

There is a desire to harmonise systems of mass tort style claims and ensure redress is available across the EU, making access to justice easier both within countries and cross border. The road to such a system has been far from easy and the path remains littered with obstacles.

The current position across the EU is diverse. Some countries have mature collective redress systems, others have none and there is of course a range in between. The mechanisms for collective redress, where available, can also differ greatly from country to country.

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Concerns abound in relation to the current proposals. Some of the issues raised include:

- The potential for forum shopping.
- Transparency, or the lack of transparency, in relation to funding.
- Avoiding the creation of conflicting regulatory frameworks which may happen where existing collective redress mechanisms are already in place.
- Ensuring commonality is required as a prerequisite to qualify as part of a collective redress action.

Such concerns have been put to the European Commission to consider before the Directive is finalised.

As it is likely that the Directive for Representative Actions will come into force after the Brexit transition period, it will not apply in the UK unless specific action is taken by Parliament to incorporate it into domestic law.

In England and Wales there are already mechanisms for the management of mass tort actions. Not only are Group Litigation Orders available, but the Consumer Rights Act 2015 has also introduced a collective proceedings regime which applies to a relatively narrow area in relation to claims brought in the Competition Appeals Tribunal. Unlike Group Litigation Orders, the collective proceedings regime can operate on an opt-out basis, meaning that group actions can be brought without identifying each and every individual claimant.

Further information

To find out more about our services and expertise, and key contacts, go to: **kennedyslaw.com**

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