Medical Devices

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Presentation content

Why medical devices matter

(to liability underwriters)

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Why do medical devices matter to liability underwriters?

Size/complexity of claims - mass tort potential

Have driven recent UK case law in relation to defective products

Have the potential to contribute to increasing volumes of group litigation in the EU

Why do medical devices matter to liability underwriters?

A sample list of medical mass tort claims from a US claimant firm website

1. Taxotere – pharma – breast cancer chemotherapy product- alleged failure to warn of hair loss
2. Opioids – pharma – painkillers – alleged failure to warn of addictiveness and side effects
3. Surgical mesh – medical device – various alleged injuries
4. Essure – medical device – sterilisation – alleged pain and injury
5. Xarelto – pharma – anticlotting drug – alleged internal bleeding/death
6. IVC (inferior vena cava) filters - medical device – anti blood clotting device – alleged injury
7. Valsartan – pharma – hypertension and cardio drug – alleged contamination with carcinogens

https://daileylawyers.com/blog/7-current-and-future-medical-mass-torts/

Why do medical devices matter to liability underwriters?

Other historic examples

Breast implant claims.

- PIP

Hip implant claims

- Resulted in significant recent case law on defect under Consumer Protection Act 1987.

What is a medical device?

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What is a medical device?

A broad range of products:

> *A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose."* World Health Organisation

- Defined in law and categorised under various regulatory regimes globally of which the most significant are the US and EU regimes.

- The UK regime is based on EU law implemented during the UK's membership of the EEC/EU but does not incorporate the two current key regulations that apply in the EU.

What is a medical device?

Regulatory categories under old EU directives

General Medical Devices

E.g. heart valves, syringes, first aid bandages, CT scanners, dialysis machines, and any software

Active Implantable Medical Devices (AMIDs)

Any medical device implanted in the patient and requires a power source

E.g. pacemakers, neurostimulator, and insulin pump

In Vitro Diagnostic Medical Devices (IVDs)

Any medical device which used alone, or in combination, is used to conduct tests on human samples from the human body

E.g. COVID-19 tests, blood type identification, and cancer screening

Big business

"The global medical devices market attained a value of about USD 562.6 billion in 2022. The market is further expected to grow at a CAGR of 6.2% during the forecast period of 2023-2031 to reach a value of about USD 965.2 billion by 2031." (Businesswire, 23 March 2023)

- Technological advances
- Aging populations
- Increasing prevalence of chronic diseases
- Opportunities in emerging markets
- Regulatory environment
- Litigation exposures

Key features of EU and UK regulatory regimes

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Relevance of regulation

- Governs how a device may be brought to market.
- Categorises devices by risk.
- Imposes post-market obligations on manufacturers including adverse event/incident reporting and post-market surveillance.

Medical Device /In Vitro Diagnostic Medical Device

EU MDR/ EU IVDR

- Regulation (EU) 2017/745 – "MDR" and Regulation (EU) 2017/746 (in vitro diagnostic devices) govern the clinical investigation and sale of medical devices for human use. Manufacturers must comply when placing products on the market.
- MDR repealed Directive 93/42/EEC (medical devices) and Directive 90/385/EEC (active implantable medical devices) and has been of application since 26 May 2021. Regulation 2017/746 repealed Directive 98/79/EC and has applied since 26 May 2022.
- Devices certified under the old directives must be recertified under the new regulations by the end of relevant transition period.

The EU regulatory regime

Approval for release to market

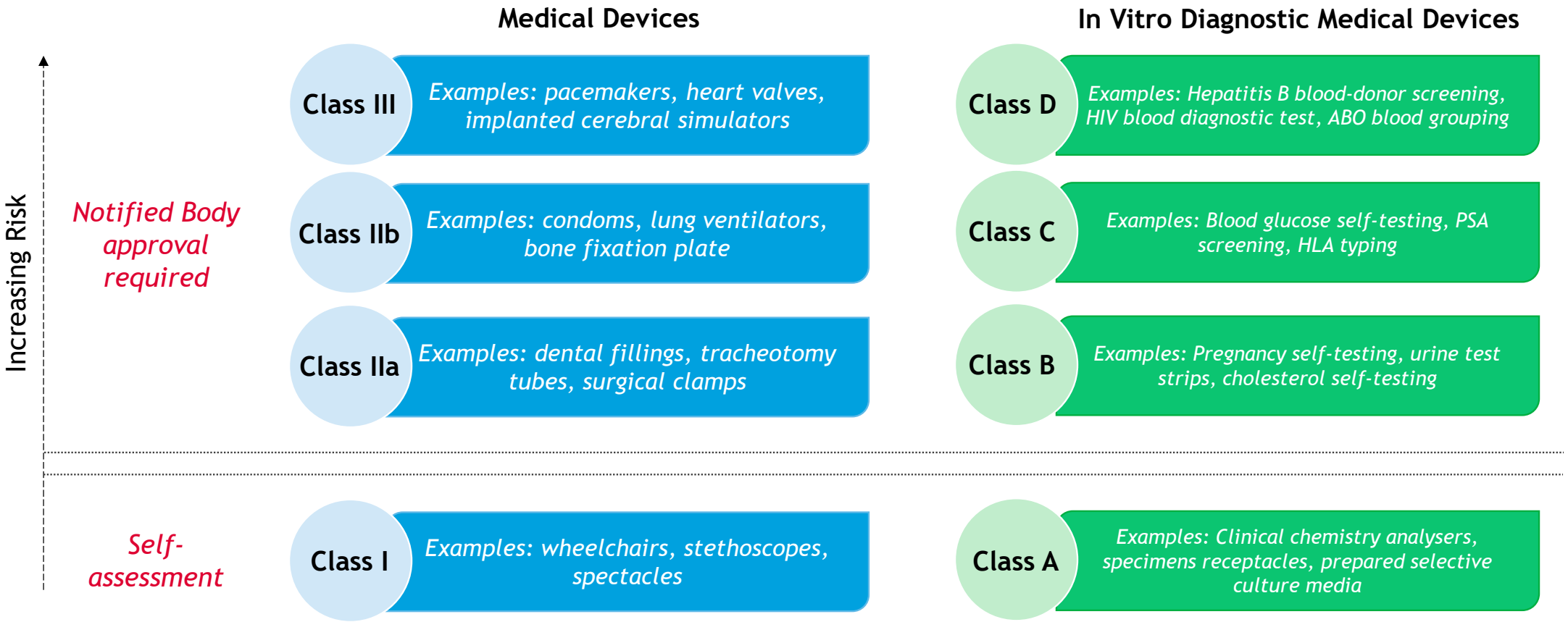
- Manufacturers put a CE mark on a medical device once it has passed a conformity assessment.

- Usually involves an audit of the manufacturer's quality system + a review of technical documentation from the manufacturer on the safety and performance of the device (subject to device categorisation).

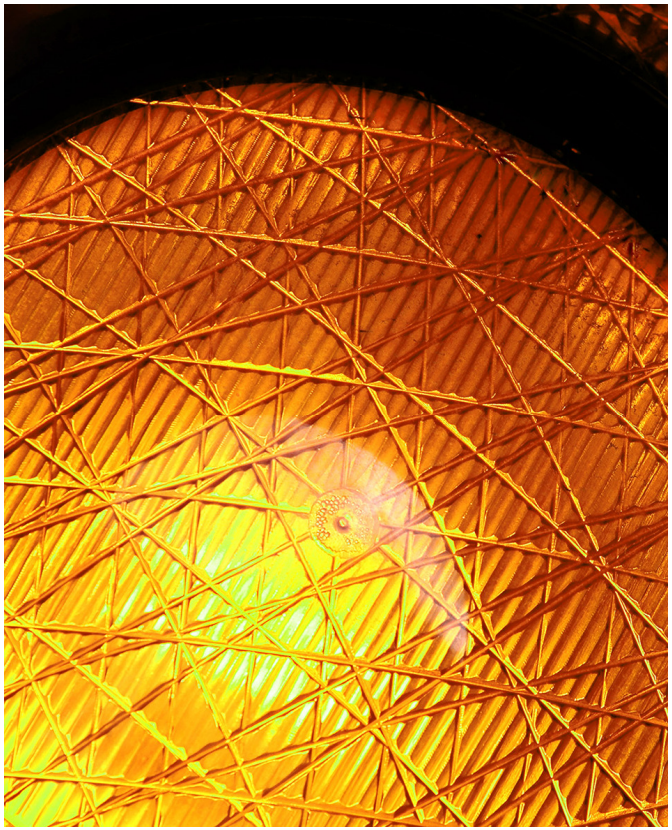
- Member States designate accredited “notified bodies” to conduct conformity assessments. Depending on the risk categorisation, the notified body may before issuing CE certificate have to:
  - request the opinion of specific expert panel.
  - seek a scientific opinion from the European Medicines Agency.

Classification by risk

Medical devices and IVDs



PMS, Vigilance and reporting



Post-market surveillance - manufacturers as part of QMS must have a system to actively and systematically gather, record, and analyse relevant data on the quality, performance, and safety of a device throughout its lifetime.

This data needs to be recorded and analysed to determine any necessary corrective or preventive actions that the manufacturer needs to implement, as well as monitor the effectiveness of such actions. Can be a focus of disclosure in litigation.

Vigilance - MDR and IVDR reporting requirements include notification and evaluation of “Incidents” and “Field Safety Corrective Actions” (FSCAs) involving medical devices. May prompt withdrawal of product or recall.

UK position

Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which transposed:

Directive 90/385/EEC on active implantable medical devices (EU AIMDD)

Directive 93/42/EEC on medical devices (EU MDD)

Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

In Great Britain the current route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation. EU MDR and EU-IVDR were however not retained by the EU (Withdrawal) Act 2018 and therefore do not apply in Great Britain. The UK plans to legislate in coming years bringing the GB PMS regime closer to the new EU model.

UK position

The regulator - Medicines and Healthcare Products Regulatory Agency

The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK.

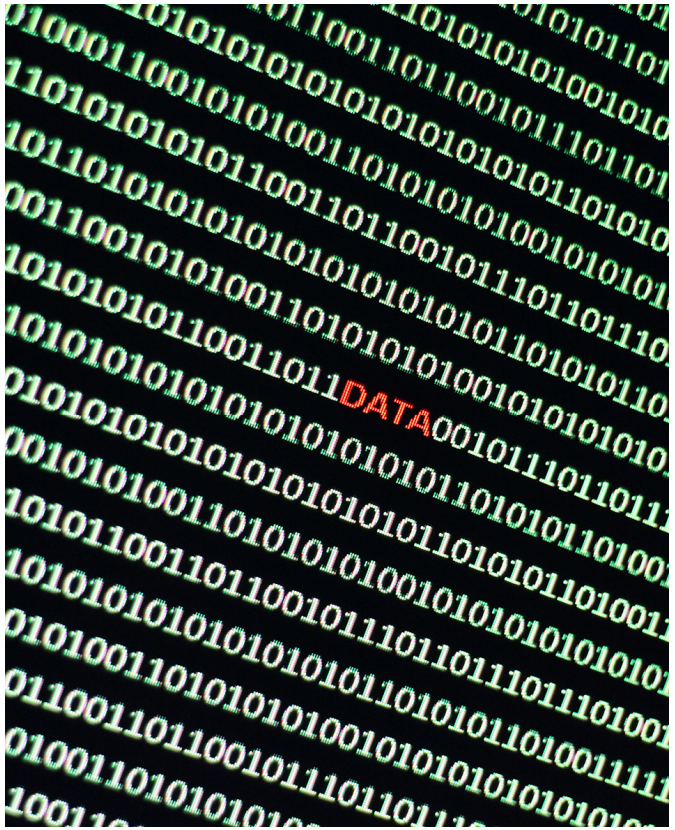
The MHRA is responsible for the designation and monitoring of UK conformity assessment bodies.

Devices sold in the UK must be registered with the MHRA by a UK based manufacture or by a UK Responsible Person for a manufacturer based outside the UK.

Future Developments

The regulator - Medicines and Healthcare Products Regulatory Agency

The US Consolidated Appropriations Act was signed into law on 29 December 2022, which requires medical devices which meet the definition of a ‘cyber device’, i.e. devices with software installed; have the ability to connect to the internet and have technical characteristics that could result in a vulnerability to cybersecurity threats, to mandate risk management of medical devices.



Under Regulation (EU) 2022/123, medical device manufacturers are required to implement cybersecurity risk management; appropriate corporate governance processes for the oversight and assurance of cybersecurity risks; evaluate control effectiveness and attest to the effectiveness of the risk treatments performed.

Liability and defect - the UK position

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Liability

Claims may be brought in tort or on the basis of the “no-fault” statutory regime under the Consumer Protection Act 1987 (CPA), which implemented the Product Liability Directive 85/374/EEC.

CPA claims are usually preferred because claimants do not have to establish fault on the part of the producer. Instead, they need to prove in their claim that:

- The product was defective,
- The claimant suffered damage (injury), and
- There was a causal link between the defect and the damage suffered.

Defect may be of design, manufacture or failure to warn.

Defect under the CPA

A product is ‘defective’ “[i]f the safety of the product is not such as persons generally are entitled to expect … in the context of risks of damage to property, as well as in the context of risks of death or personal injury” (s.3(1) of the CPA).

Considered in 3 recent metal-on-metal hip prosthesis cases:

Wilkes v Depuy International Limited [2016] EWHC 3096 (QB), [2018] QB 627

Gee v Depuy International Limited [2018] EWHC 1208 (QB).

Hastings v Finsbury Orthopaedics Ltd [2022] UKSC 19, [2022] S.L.T. 771.

Entitled expectation

- *"Safety is inherently and necessarily a relative concept, because no product, particularly a medicinal product, if effective, can be absolutely safe… The public is not entitled to expect that a product which is known to have inherently harmful or potentially harmful characteristics will not cause that harm, especially if … the product cannot be used for its intended purpose without incurring the risk of that harm materialising".* [Gee at 110]

- *"The test is not what is expected but one of entitled expectation"* – Hastings at 15(ii)

- The assessment of the risk must be done at the time the product is supplied and not with the benefit of hindsight. However, the court is entitled to have regard to everything now known about the device, irrespective of whether that information was available at the time it was put on the market or has come to light subsequently.

Causation

It is unnecessary for the judge to ascertain the precise cause of the defect - Ide v ATB Sales Ltd [2008] EWCA Civ 424 at [7].

A claimant might have to identify a precise defect in order to show a causal link.

Claim will often be brought on the basis that the defect has caused an increased risk of harm.

What is then required to be shown in relation to the increase of risk on the basis of the epidemiological or bio-statistical evidence?

Statutory defences

- 6 defences of which the most likely to be potentially relevant is:
- Development risk defence: *"the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control"*.
- Not the first line of defence. Supposes defect already found.
- Considerable legal controversy on scope and application.

Considerations

- Risk-benefit, avoidability and cost may be potentially relevant considerations.
- A claim may be more likely to succeed where a product does not meet its own specifications.
- Compliance of a product with a regulatory regime may make it more difficult for a claimant to prove defect (Wilkes) but is not an automatic defence. Failure to comply with a regulatory regime or applicable standards may not be indicative of defect (Pollard v Tesco Stores [2006] EWCA Civ 393).
- Boston Scientific Medizintechnik GmbH v AOK Sachesen-Anhalt (C-503/13 and C-504/13) - where it is found that products belonging to the same group/ production series have a potential defect, it is possible to classify all of them as defective, without needing to show that the particular product in question is defective.

Common features of claims

- Claims are personal injury claims (with corresponding costs and limitation rules, subject to 10 year longstop under CPA). Burden of disclosure is overwhelmingly on the defendant.
- The role of the learned intermediary may be relevant to the defence.
- A range of expert evidence is needed and evidence on the performance of a device with a comparator device or treatment may be required. Costs are commensurate with complex litigation. Likely to proceed by way of lead cases.
- Claims may be driven by third party funders.
- Claims relating to the same device may be brought in multiple jurisdictions.

The new EU landscape

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New EU legislative landscape

- New Product Liability Directive – final form and content not yet determined.
- New Collective Redress regime.
- Litigation funding is not widespread per the UK or US experiences. EU institutions generally do not want to see that change.
- The position will vary very considerably between member states.

Trends

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What will we see more of?

- Medical device manufacturers will continue to be key target for claimant firms and third party litigation funders.
- Classes of products will be attacked rather than specific devices of individual manufacturers – few but bigger claims?
- Nature of allegations will expand in relation to products already subject to litigation.
- There will be scrutiny by claimants on product development, clinical evaluation and regulatory approval.
- Digital technologies may be a springboard for new claims.

Any Questions?

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