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MEDICAL DEVICE REGS: GETTING IT WRONG

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GETTING IT WRONG

- MHRA Enforcement – now and in 2020
- Damages (Contract and Negligence)
- Vicarious liability

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2020 Enforcement

Key changes under MDR/ IVDR 2017 (MHRA/ .gov website):

- correctly classified against the new risk classification criteria
- general safety and performance requirements met, (labelling, technical docs and QMS)
- increased requirements for clinical evidence
- manufacturer has responsible person for regulatory compliance
- economic operators in the supply chain are compliant
- Sufficient financial coverage in respect of a manufacturer's potential liability
- the new vigilance reporting timescales, annual periodic safety update report

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MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

MHRA Mission Statement:

"To enhance and safeguard the health of the public, by ensuring that medicines and medical devices work and are acceptably safe."

- MHRA Enforcement Strategy 2010

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MHRA FUNCTION

Not interested in individual claims

Principle aim is to achieve compliance through:

1. Advice and guidance

2. Risk-based inspection

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MHRA POWERS

1.Inspect goods
2.Examine manufacturing and testing arrangements
3.Requisition and copy records
4. Seize evidence

- CPA 1987, s.29

5. Recall medical devices

- Consumer Product Safety Regulations 2005, R.15

6. “Directed Surveillance”

- Regulation of Investigatory Powers Act

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MHRA SANCTIONS: MDRs

<u>COMPLIANCE NOTICE (Reg 62)</u>

- Non-conform to essential requirement, but no H&S compromise

<u>RESTRICTION NOTICE (Reg 62)</u>

- Supply restricted for H&S reasons

<u>£5,000 fine and/or 6 months imprisonment</u>

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MHRA SANCTIONS: CPA 1987

- Breach of Safety Regulations
- Prohibition Notice
- Notice to Warn
- Suspension Notice
- Forfeiture Notice

- CPA, ss 12-17

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DEFECTIVE GOODS UNDER CPA

- Liability incurred by the "producer" (manufacturer or supplier)
- Device is defective if "not as safe as persons are generally entitled to expect" (s.3)
- Assessed by considering all circumstances relating to supply, including packaging and instructions.

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DEFECTIVE GOODS UNDER CPA

- Liability is a matter of strict liability.

- Defect + injury is enough to create an offence

- Intention, knowledge and processes are not irrelevant

- Two relevant defences:
  - The defect was not present when the device was supplied
  - Technically, you could not have known about the defect.

- Needn't be "medical". General Product Safety Regulations 2005 apply in addition to MDR 2002

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NEGLIGENCE AND CONTRACT

MHRA goes after your regime

NHS (hospitals) and patients go after your cash

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NEGLIGENCE AND CONTRACT

A civil claim by a business or individual with four elements

1. Legal duty: Contract obligation or duty of care

2. Breach of duty

3. Damage to claimant

4. Damage caused by breach of duty

THIS IS A CLAIM FOR DAMAGES AGAINST YOUR BUSINESS

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DAMAGES

"Restitutio in Integrum"

- Damages should (so far as a money can) place the claimant in the same position as if breach hadn't happened

- But not all losses. Need an element of forseeability

- Make good an injury
- Reputation?

- Make good a financial loss
- Loss of profit, goodwill?

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VICARIOUS LIABILITY

- Employer is liable for the conduct of an employee…

….but only if “in the course of employment”

- So an employer is liable for things done in the course of employment (even mistakes)…

…but not for “frolics”

DANGER OF PERSONAL LIABILITY !

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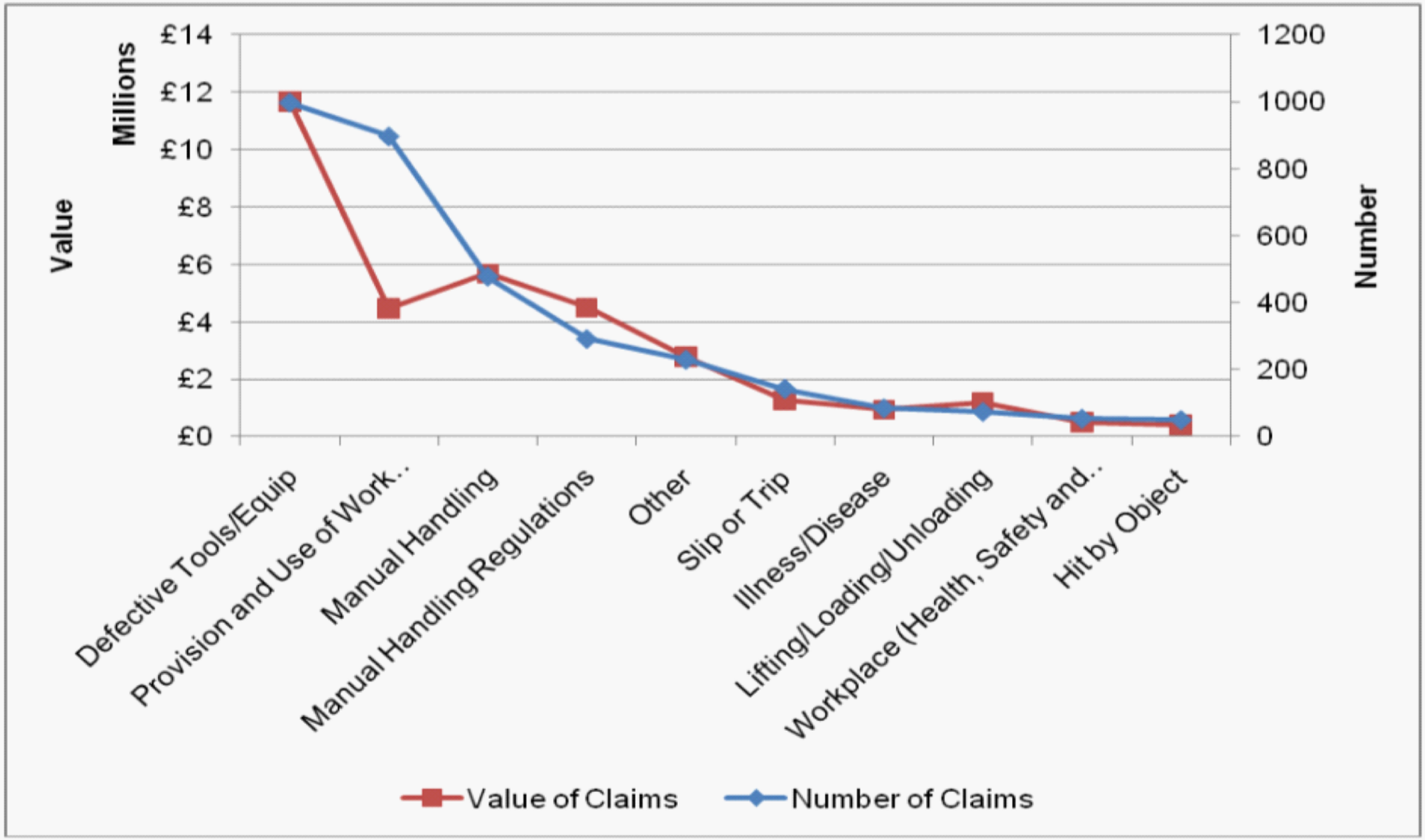
Fig. 2. Top Ten Claims, Identified as Related to the Operation and/or Maintenance of Medical Devices and Equipment, RPST, April 1999 – July 2010



NHS Litigation Authority, July 2010

SUMMARY

- MHRA enforcement: aimed at companies, aimed at processes
- Contract and negligence claims: right of affected individual to make cash recovery
- Cash recovery is damages, and rules apply
- Individuals can be made personally liable

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Thank you for listening

Any QUESTIONS?

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