MDR Business Impacts and MedTec Market

• The leading medical technology industry association in the UK
  • A community of over 265+ members
• We champion the use of safe and effective medical devices

We are the voice of the industry
• We are an authoritative voice, communicating the interests and issues of our members.
• We are recognised as building trust and cooperation between industry and our partners.

We are the support that powers industry
• We provide insight and expert assistance
• We outline industry’s strategic vision, contributing to the development of policy in areas such as regulation, procurement and technology adoption.

We facilitate collaboration and help businesses prosper
• Member-led groups address a wide variety of topical issues.
• We run international trade missions and provide support for UK companies in overseas markets.

All our work is underpinned by a robust Code of Business Practice, accepted by each member organisation, which drives a commitment to high ethical practices by all
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MISSION
Champion the benefits and use of safe & effective medical technologies to support high quality patient outcomes and health system efficiency

STRATEGY
Advocating health & business policies and providing intelligence & guidance so members operate effectively in a favourable business environment

UK Market
Enabling rapid evaluation, reimbursement & adoption
Commercial & Market Access Strategy
Procurement
Commissioning
Digital Health
Tariff & incentives

Economic Growth
Enabling business growth: UK & international
Industrial & Trade Policy
Skills
Funding
Exhibitions & delegations

Regulatory
Supporting simple and smart regulation
Interface with MHRA
Industry Leadership with EU

Ethics & Compliance
Conducting business in the right manner
Code of Practice
Legal Policy

OUR VALUES
Collaborative, Accountable, Integrity, Ambition
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Agenda

• Business Connection
• Clinical Evidence
• Post-Marketing Surveillance Requirements
• Economic Operators and Supply Chain
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Business Connection

• Transition Period Management
• Liabilities
• Quality Management System requirements
• Integration of Risk Management
• Supply Chains
• Transparency
Clinical Evidence

- Clinical Evaluation Report
- Summary of Safety and Clinical Performance
- Clinical Equivalence
- Scrutiny Procedure
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Post-Marketing Surveillance Requirements

- Vigilance vs. PMS
- Product Safety Update Reports
- Links with Risk Management
- Product Lifecycle Management
- PMCF plans
Economic Operator Requirements

- Person Responsible for Regulatory Compliance
- Roles for:
  - Manufacturer
  - Authorised Representative
  - Distributor
  - Warehouse
Conclusions

- Business Focus
- Holistic process
- Work on Clinical aspects – NOW
- Brexit impacts?
Phil Brown

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