



**Association of British Healthcare Industries**

# MDR Business Impacts and MedTec Market

MDMA Meeting

Phil Brown 20<sup>th</sup> February, 2018



# 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



# MDR Business Impacts and MedTec Market

## 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



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## 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



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## Economic Operator Requirements

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





# MDR Business Impacts and MedTec Market

## Conclusions

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



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