Packaging implications of the EU Medical Device Regulations

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ANDREW LOVE
VP Capability Development
Be4ward Ltd

Introduction

Be4ward

- A niche management consultancy with award winning success in delivering artwork capability.
- We provide specialist consulting services to the global pharmaceutical, biotech and medical device industry.
- Our team combines operational management experience, subject matter expertise and excellent consulting skills to help our clients deliver successful change.
- Whilst we have in depth knowledge of the supply base in our areas of focus, we provide independent advice to our clients.
- Our current areas of focus include:
  - Packaging and artwork management.
  - Product complexity management, late customisation and postponement.
  - Product coding, UDI, serialisation and anti-counterfeiting
  - Secondary packaging supply chain design.
  - Post merger legal entity and brand integration.

Andrew Love

www.andrewrlove.com

- Vice President, Be4ward Ltd
  - assisting a number of Pharmaceutical, Biotech, Medical Device and Healthcare clients with packaging management related engagements.
- Prior: Global head of pharmaceutical packaging for GlaxoSmithKline.
  - Led re-engineering of GSK's product change management capability.
  - Established GSK's global packing design capability.
  - Led definition of GSK's strategy for serialisation, authentication, anti-counterfeiting and product coding.
  - Led development of GSK's Global Packaging Strategy.
- Previous: GSK and specialty chemical industry.
  - Various engineering, supply chain and operational roles.
- Masters Degree in Engineering, MBA and Chartered Engineer.
- Based in London, UK. Contact details: andrew.love@be4ward.com, +44 203 318 0939.

Our team have won many awards for their work, including the establishment of a world class global artwork capability for a Top 3 Pharma Company.

The regulations on medical devices and In vitro diagnostic devices are undergoing the most significant change for decades

- What is happening
  - Medical devices and in vitro diagnostic devices are important to our health and quality of life.
  - The European Commission is introducing changes to the Medical Device Directives (MDDs).
  - This will result in a total new Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).
  - These are a complex array of regulations weighing in at 566 and 477 pages respectively.
  - They move the governance model to one more like Pharma.
  - Many changes that will impact anyone designing, manufacturing, testing, approving and marketing medical devices into the EU.

- Why
  - Consequence of recent events and a requirement to ensure that they could not happen again.
    - Poly Implant Prothèse breast implant scandal.
    - Metal-on-metal hip implants scandal.
  - Current rules on the safety and performance of medical devices in the EU were harmonised in the 1990s and the above incidents exposed weaknesses in this framework.
  - Need to restore confidence of patients, consumers and healthcare professionals in the safety of medical devices.

"We should not wait for another scandal instead we should start a discussion on how to strengthen European oversight…"

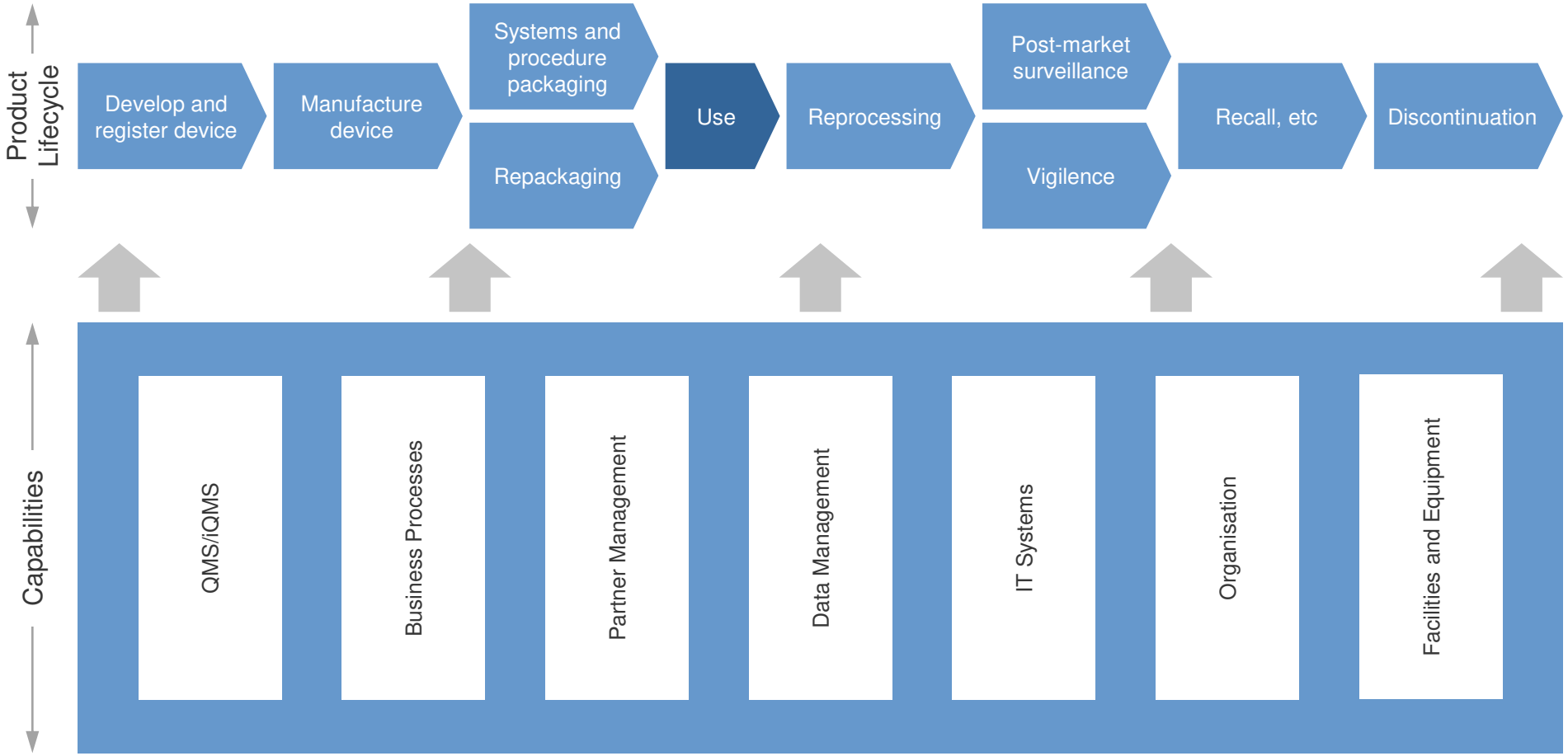
Elżbieta Bieńkowska
Commissioner for Internal Market,
Industry, Entrepreneurship and SMEs

There are a number of objectives the legislation seeks to address and timelines have started

- The aim of the revisions was to ensure:
  - a consistently high level of health and safety protection for EU citizens using these products;
  - the free and fair trade of the products throughout the EU;
  - that EU legislation is adapted to the significant technological and scientific progress occurring in this sector over the last 20 years;
  - Revisions included: the extension of the scope of legislation, better supervision of independent assessment bodies, clear rights for economic operators, and stronger requirements for clinical evidence.
- Status and timelines
  - The legislation has been passed by the European Council (7 March 2017) and the European Parliament (5 April 2017).
  - Expect to be formally published in May 2017 and come into force early June 2017.
  - New rules established under MDR will apply in 2020 (3 years).
  - New rules established under IVDR will apply in 2022 (5 years).

Impacts all medical device and in vitro diagnostic devices marketed in the EU and all medical device and IVD companies supplying products to the EU including Pharma companies supplying combination products.

The EU MDR/IVDR legislation impacts the whole lifecycle of medical devices that are marketed in Europe…



…and requires many new or modified capabilities.

There is a complex group of actors who are impacted…

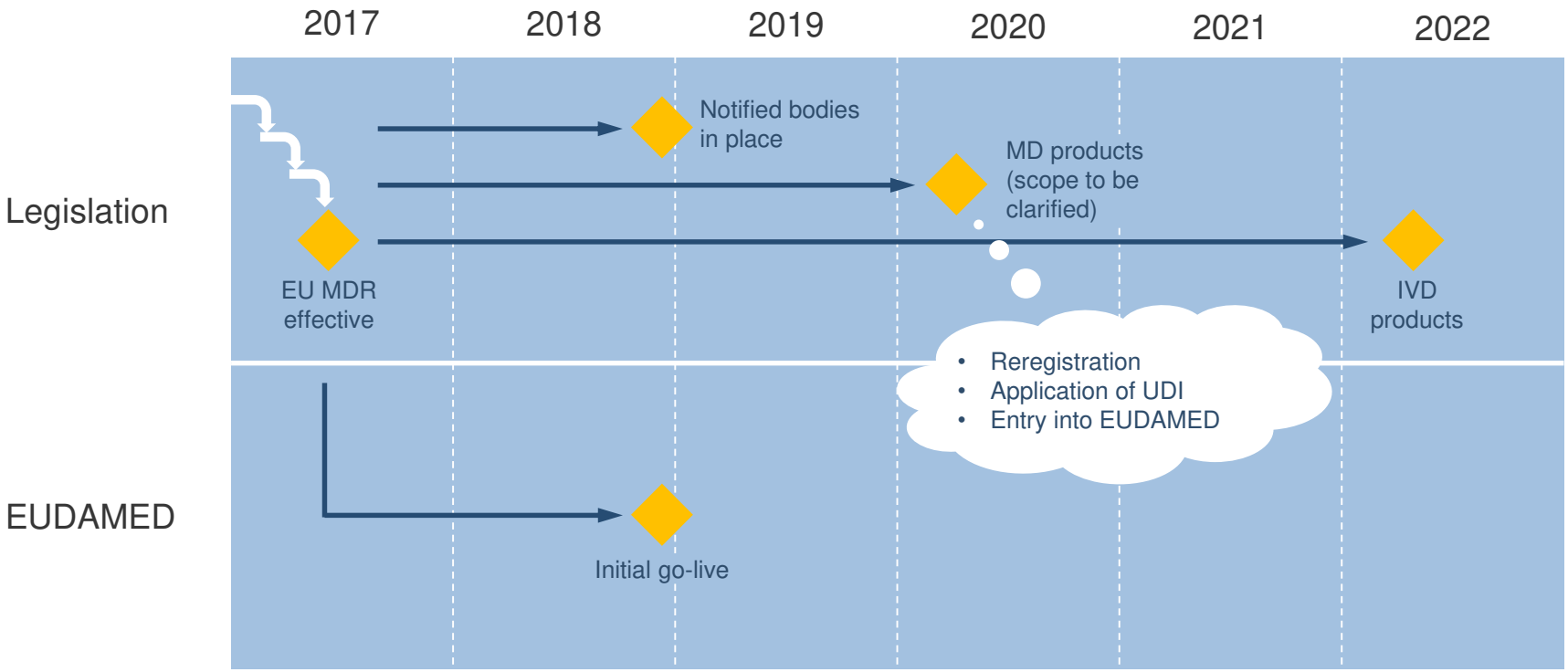
EU MDR/IVDR Actors

Device manufacturers	Qualified person	Importer
Systems and Procedure Packagers	Authorised representative	Distributor
Repackers		Health Institution?
Reprocessors		
Parts Suppliers		

Committee on Medical Devices	National Authority	Notified Body	EUDAMED Team
Medical Device Coordination Group	Competent Body	Reference Laboratory	EUDAMED Steering Group

…each of whom are impacted differently by the legislation.

Whilst still evolving, timelines for the implementation of the EU MDR/IVDR Legislation are very challenging



Companies need to understand the impact of the legislation and plan for it now.

The EU legislation introduces some significant changes to the way the EU marketed MD/IVD lifecycle needs to be managed

Some of the key changes

- Scope and classification of products.
- Common Specifications.
- Technical files and Declarations of Conformity.
- Clinical evidence, vigilance and post-market surveillance.
- Obligations of Economic actors and subsequent liabilities.
- Quality Management Systems.
- Requirements for a Qualified Person.
- Notified Body supervision and re-designation.
- Unannounced Audits.
- Introduction of the Medical Device Coordination Group.
- UDI to improve Traceability and Transparency.
- EUDAMED database.
- Portfolio rationalisation/elimination of unnecessary products.

Some industry experts are concerned that the increased cost of meeting these requirements will reduce the degree of innovation with products in the EU.

The new legislation will present a number of packaging challenges

Three key challenges

- Product re-registration
  - Grandfathering of registrations from legacy products to the new regulations is considered unlikely by many experts due to the new requirements with technical documentation and testing.
  - This may change artwork content and require artwork updates for products being re-registered.
- Labelling content
  - The regulations specifically define content that should be included in the product labelling.
  - Companies will have to audit their packaging artwork and labelling to ensure they meet these requirements and update accordingly.
- Adoption of UDI marking
  - Whilst the adoption of UDI will have impacts beyond packaging there are a number of considerations with packaging.
  - The placement and application of the UDI.
  - Space on the artwork for the UDI.
  - Where required application of the UDI to the device as well as the packaging.

Notwithstanding the rest of the regulations, these alone could present a significant change programme for manufacturers.

Summary

- The new regulations for medical devices and IVDs are not coming — they have arrived.
- The present the biggest change to the regulatory framework in decades and will impact all Economic Operators supplying product to the EU.
- The requirements being introduced are wide-ranging and move the governance model to one more like Pharma.
- These will require new and updated capabilities and processes, new relationships, changes to product registrations, testing and monitoring.
- A result of these requirements are likely updates to all product packaging.

It is important to have a clear implementation plan to ensure you transition to these new requirements.

THANK YOU

Contact details

Andrew.love@be4ward.com

48 Warwick Street, London, W1B 5AW, UK
0800 098 8795, 0203 318 0939

Montreal, Canada: 888 308 8657