The Future of Regulation

SEHTA MedTech Expo

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Where are we?

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Post transition:

- Section 3 of European Union (Withdrawal) Act 2018 – converts existing ‘operative’ EU law into UK domestic law
- EU law no longer of direct effect
- Various provisions in EU-UK Trade and Cooperation Agreement of relevance to health and life sciences

- Government previously sought close future relationship with EU institutions, including EMA
  - March 2018: would seek to become ‘associate member’ of EMA (though cf Council response)
  - November 2018 Political Declaration: parties would “explore possibility of cooperation” with EU agencies such as EMA
- Repeated industry and Parliamentary calls for close alignment and mutual recognition of regulatory activities
- Concern that Government dropped commitment to maintain regulatory alignment

Where are we?

Post transition:

- New Medicines and Medical Devices Act 2021 creates new structure for UK to legislate to change/update regulations on medicines, devices and clinical trials
- No immediate change, but regulation-making powers
- Must take into account three principles in any new regulations:
  - Safety
  - Availability
  - *"the attractiveness of the United Kingdom as a place in which to develop or supply medical devices"* (or conduct clinical trials or supply medicines)

- Concerns remain about regulatory divergence

Where are we?

- Since 1 January 2021, UK is no longer part of the EU regulatory network
- MHRA has taken on responsibility for UK medical device market
- Different rules apply to different territories

- Currently applicable legislation in Great Britain:
  - Medical Devices Regulations 2002 (UK MDR 2002)

  …which implemented
  - Directive 90/385/EEC on active implantable medical devices
  - Directive 93/42/EEC on medical devices (MDD)
  - Directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

- GB route to market continues to be based on pre-EUMDR EU requirements

Where are we going?

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Consultation Timeframe

- Promised in MHRA's Delivery Plan for 2021-2023
- Launched 16 September 2021
- Closes 25 November 2021
- Aim to publish response April 2022
- New regulations in force 1 July 2023 (to align with date for CE mark transition)

Overall Aims

- To develop a future regulatory regime for medical devices which enables:
  - Improved patient and public safety;
  - Greater transparency of regulatory decision making and device information;
  - Close alignment with international best practice, and;
  - More flexible, responsive and proportionate regulation of medical devices.

Where are we going?

Key Features

- New access pathways to support innovations
- New regulatory framework for regulating software and AI as devices
- Reform of IVD regulations to update classification and include extended patient risk review
- Making the UK a sustainability pioneer through re-use and re-manufacture of devices

Where are we going?

Chapter 1: Scope of Regulations

- Proposals for amending and expanding the definitions of devices and IVDs
- Aimed at achieving two goals:
  - Improving patient safety; and
  - Closer alignment with international best practice and definitions (removing trade barriers)

- Particular proposals to:
  - Expand definition of a device to include products without an intended medical purpose, but with similar function and risk profile (eg cosmetic contact lenses);
  - Expand definition of IVDs to include software and other products; and
  - Exclude products containing viable biological substances and exclude food.

Where are we going?

Chapter 2: Classification

- Proposals to bring greater alignment with international practice.
- More proportionate scrutiny to reflect changes in technology and better account for how devices are used – including level of invasiveness and potential toxicity.

- Specific proposals include:
  - Active implantables and their accessories becoming Class III;
  - IVF and ART becoming Class III;
  - Surgical meshes becoming Class III;
  - Devices incorporating nanomaterials becoming Class IIa-III (depending on potential internal exposure levels); and
  - Non-invasive devices which come into contact with mucous membrane becoming Class I-IIa, depending on intended use.

Where are we going?

Chapter 3: Economic Operators

- Proposals to strengthen accountability of manufactures, importers and distributors.

- Specific proposals include:
  - Requiring manufacturers to hold liability insurance to ensure adequate compensation;
  - New requirements for ‘in house’ manufactured devices;
  - New requirements for distance selling via electronic means (eg via websites and app stores);
  - Rules governing for advertising/promotional claims made about safety, performance and intended purpose;
  - Additional detail about manufacturer’s QMS requirements
  - Additional requirements for UK Responsible Persons;
  - Requirement for importers and distributors to improve traceability and safe supply;
  - New requirement to have a QP responsible for supporting regulatory compliance; and
  - Clarifying when others may take on the obligations of a manufacturer.

Where are we going?

Chapter 4: Registration and UDI

- Proposals to improve traceability and introduce a system for Unique Device Identifiers (UDIs).
- New single database for all devices on the market.
- Utilises new powers to issue public warnings under MMD Act 2021.
- Aligns with EU and US.

Chapter 5: Approved Bodies

- More detailed requirements for Approved Bodies, including UKAS accreditation
- Increased transparency of subsidiaries used by Abs
- New requirements for designation and monitoring of Abs to improve transparency

Where are we going?

Chapter 6: Conformity Assessments

- Proposals aimed at improving transparency and consistency in CAs of devices.
- Also aimed at improving robustness and efficacy of assessments to ensure safety, quality and performance.
- Especially focused on complex software and implantable devices.
- Expands requirements for content of Declarations of Conformity.

Chapter 7: Clinical Investigations and Performance Studies

- Detailed proposals for extensive changes to requirements for investigations and studies.
- Specific proposals include:
  - Tighter requirements for claiming equivalence;
  - New requirements for investigations and studies in emergency situations;
  - Clarification of application process, criteria and timeframes;
  - Exemptions for certain situations (eg small early feasibility studies), and limitations of those exemptions; and
  - New ‘Summary of Safety and Clinical Performance’ to include device information for use by patients and clinicians.

Where are we going?

Chapter 8: PMS

- Various proposals to enhance ability of both manufacturers and MHRA to identify issues, including:
  - PMS plans for how information is to be collected and assessed;
  - Clarifying requirements for reporting SUI and field safety corrective actions;
  - Ensuring manufacturers report trends of all types of incident; and
  - Defining minimum requirements for content of FSNs.

Chapter 9: IVDs

- Overall, an increase in the level of scrutiny applied to IVD devices.
- Also specifically:
  - Requirement for users of genetic tests to be provided with appropriate information on nature, significance and implications of their test;
  - Bringing CDx within regulatory scope; and
  - Removing exemption for IVDs manufactured in-house.

Where are we going?

Chapter 10: Software as a Medical Device

- Software and AI as devices have grown in market share and complexity.
- Regulatory lag, so regulations need to be revised to protect patients and support innovation.
- New definition of ‘software’ as “a set of instructions that processes input data and creates output data”.
- Also wider proposals, including:
  - New requirements for persons selling SaMD at a distance via electronic means (eg via websites and app stores) through modification of the definition of ‘placing on the market’;
  - Measures to ensure pre-market scrutiny to check safety, quality and performance of SaMD;
  - Introducing minimum requirements relating to cybersecurity; and
  - Defining specific requirements for AIaMD.

Where are we going?

Additional Proposals

- Expanding regulations to include temporarily implanted devices, and up-classifying other implantables.
- New regulatory requirements for re-manufacturing of single-use devices to ensure safety.
- Consideration of ways to make the sector more environmentally sustainable.
- New alternative routes to market:
  - ‘Pathway for innovative MedTech’ for devices that meet certain criteria (eg innovative devices, rare conditions, or SME manufacturers)
  - Route for manufacturers with a Medical Device Single Audit Programme (MDSAP) certificate, or with an approval from certain other international regulators.

“A number of the proposals set out for consideration in this consultation could bring greater alignment with requirements in … EU regulations and other international regimes rather than bringing in higher regulatory burdens for those in the medical devices industry than they face elsewhere.”