Regulating software as a medical device

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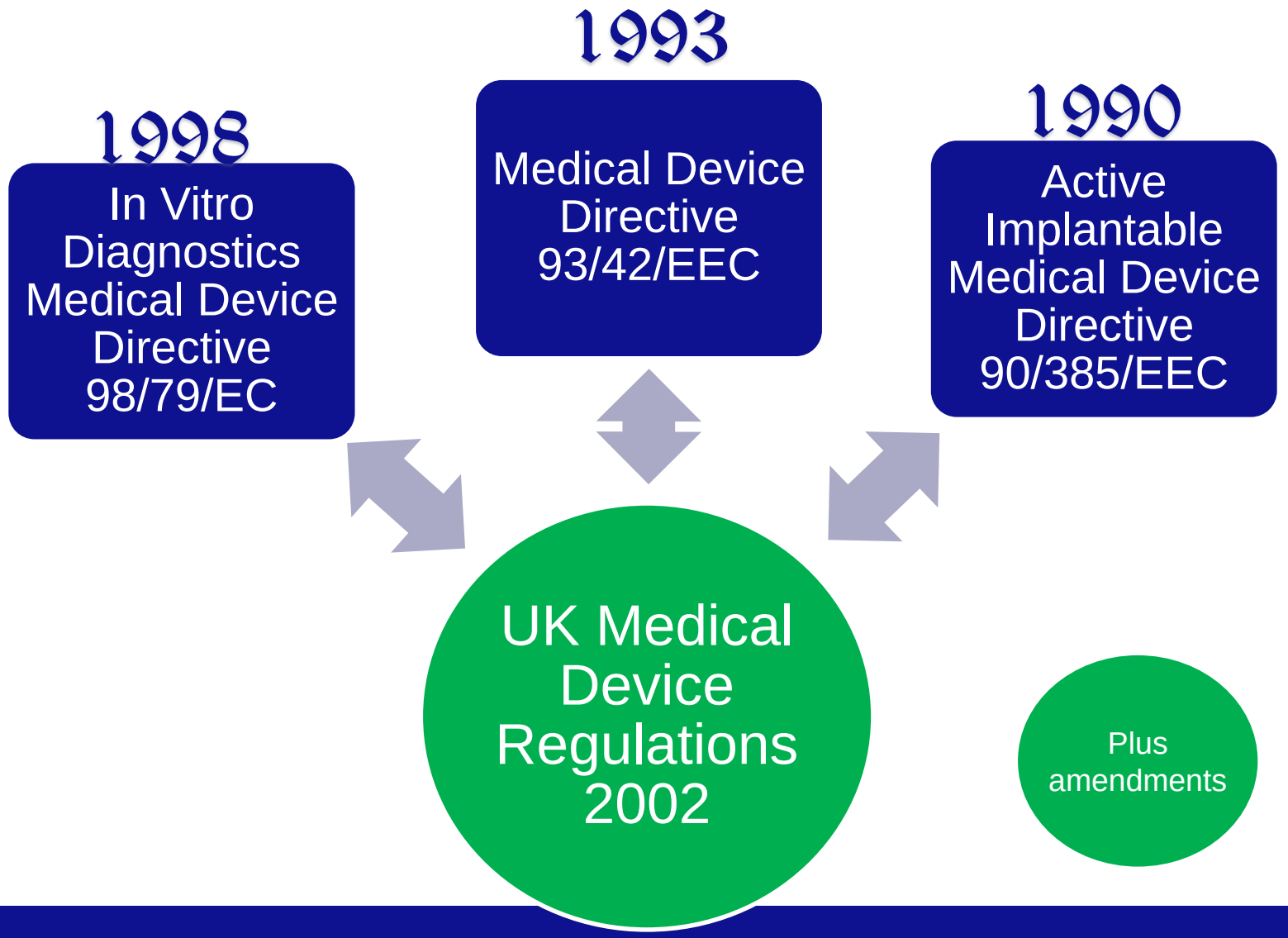
The regulatory framework



What is a software medical device?

Software, used on humans, that the manufacturer intends to be used for the purpose of:

- Prevention of disease,
- Diagnosis, monitoring, treatment or alleviation of disease, an injury or handicap,
- Compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception

IFU/labeling & “promotional materials”

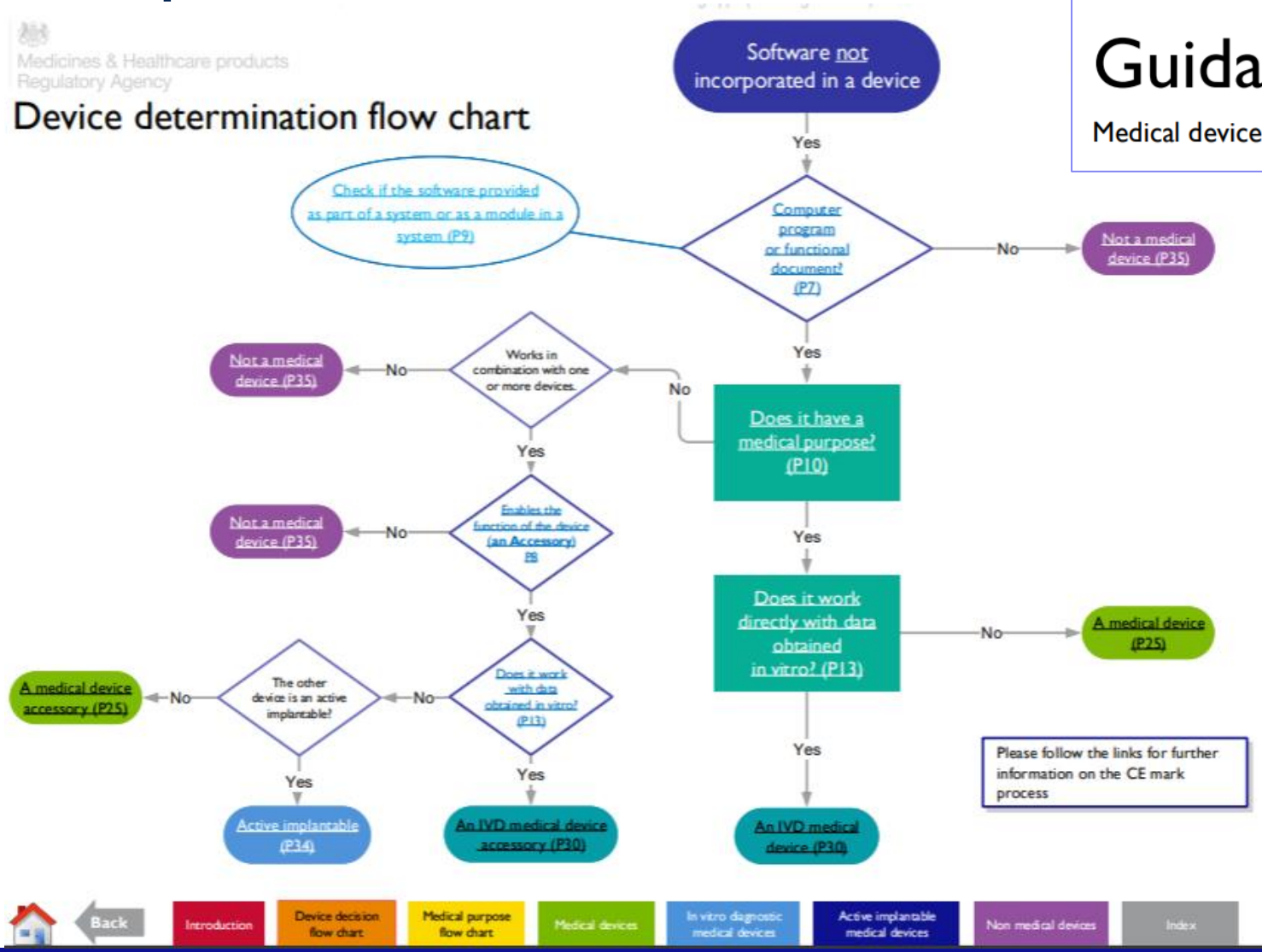
Help is at hand

Medicines & Healthcare products Regulatory Agency

MHRA

Guidance:

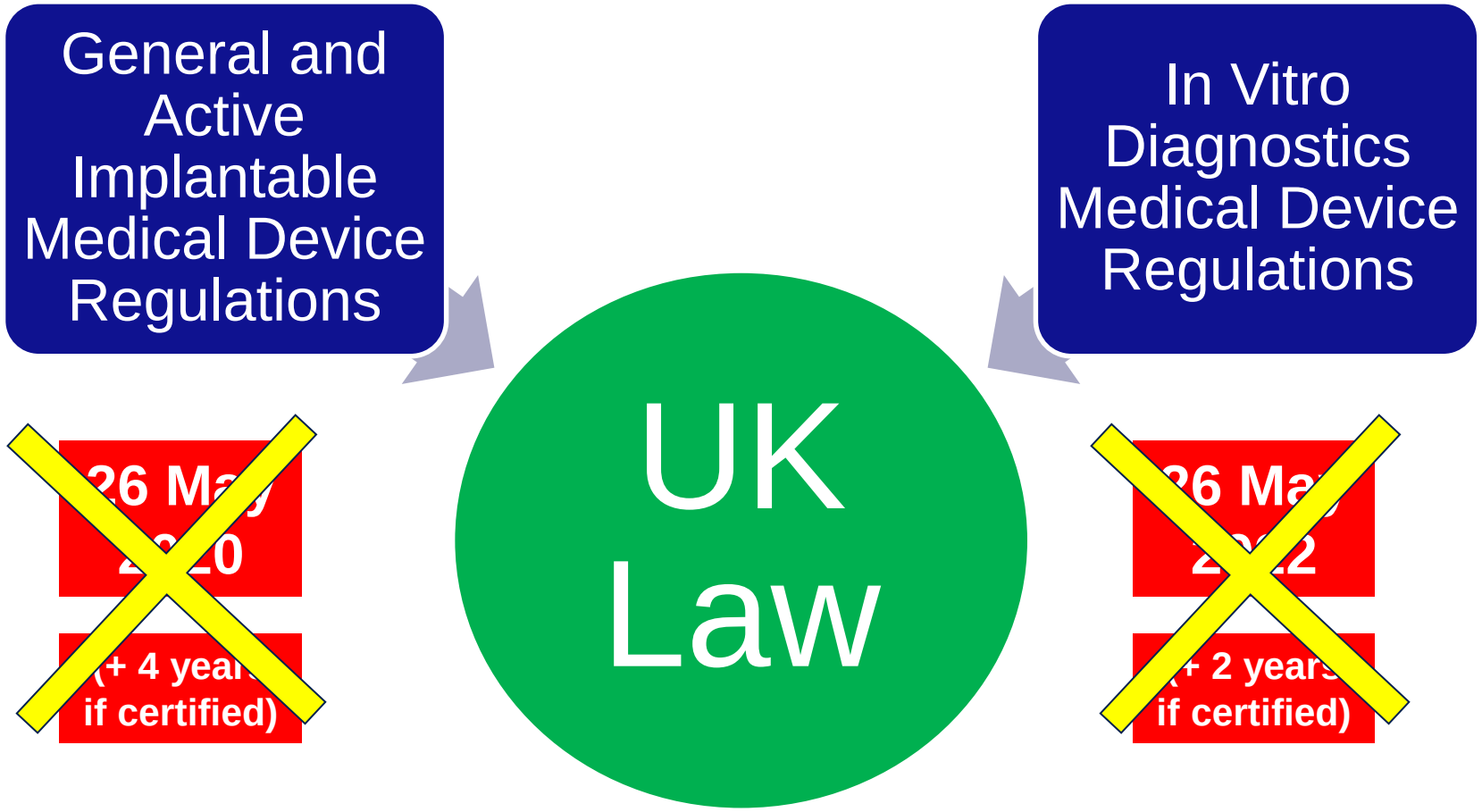
Medical device stand-alone software including apps (including IVDMDs)



Regulatory requirements

- Follow a conformity assessment route:
  - Depends on the classification of the device
  - Risk based system from I to III
  - Class I – low risk – self-certify (& register with MHRA)
  - Class IIa, IIb and III – increasing involvement by a notified body to assess the safety of the device.
- Demonstrate that it meets the relevant essential requirements
- Perform a clinical evaluation
  - Clinical trial or evaluation of relevant scientific literature or combination of both

New EU legislation was agreed in 2017 for implementation 2020



COVID-19 delay

The new regulations

Will apply to medical devices placed on the market or put into service from 26 May ~~2020~~ **2021**

Includes any major updates to existing software devices

Medical devices with a notified body certificate have up to an extra 4 years to be in compliance.

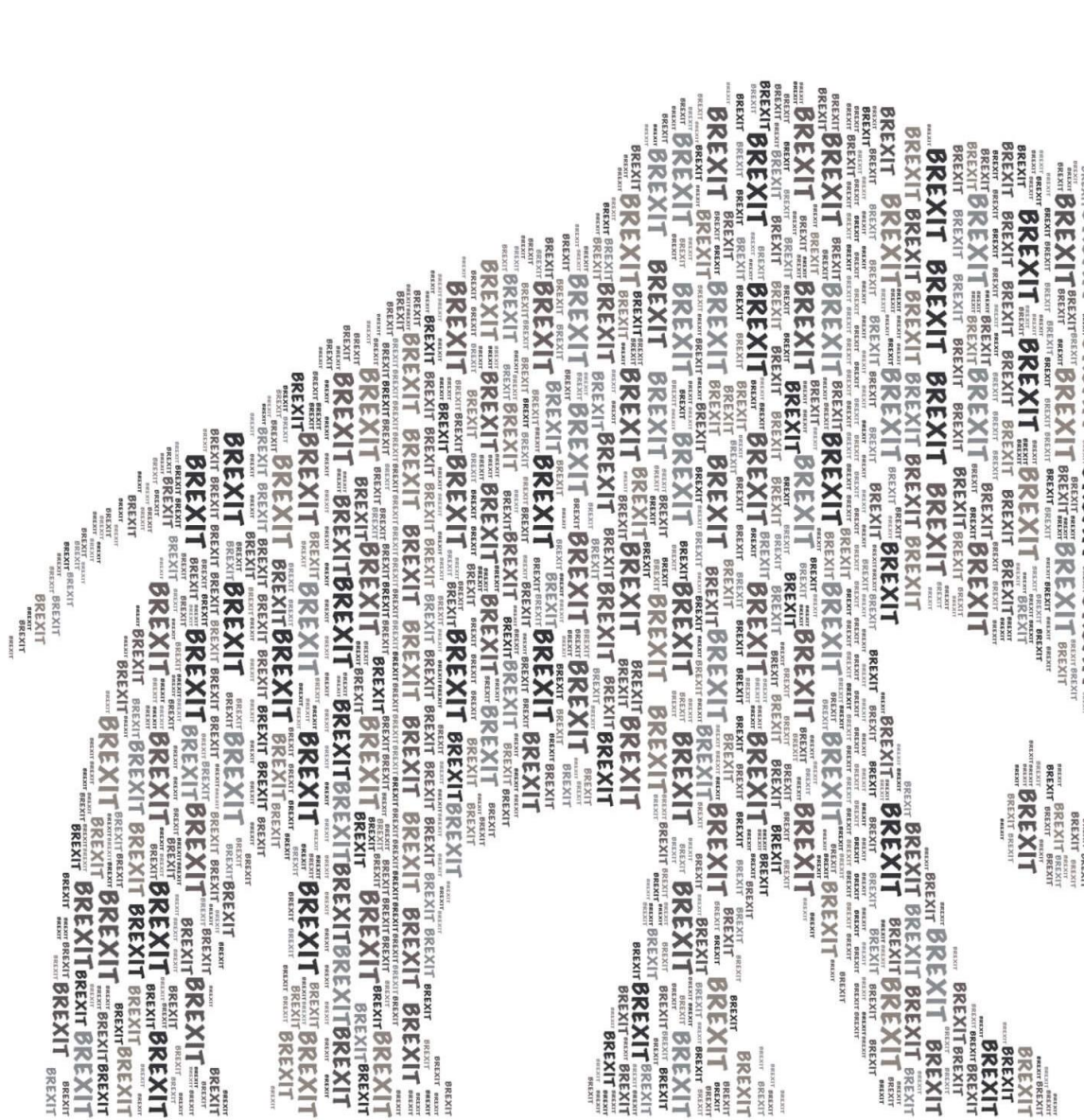
Current class I software devices will almost certainly be up-classified to class IIa or above

Changes for software?

- In house requirements - QMS!
- Essential requirements updated and will now specifically cover security and unauthorised access.
- There is a specific software rule - ☺.
- Nearly all medical device software will be at least class 2a.
- If a device is up classified from a class 1 device under the regs, it must be removed from the market until it is certified by a NB IF there is a significant change.
- Existing guidance has been incorporated into the regulations.

End of transition Dec 2020

What next?

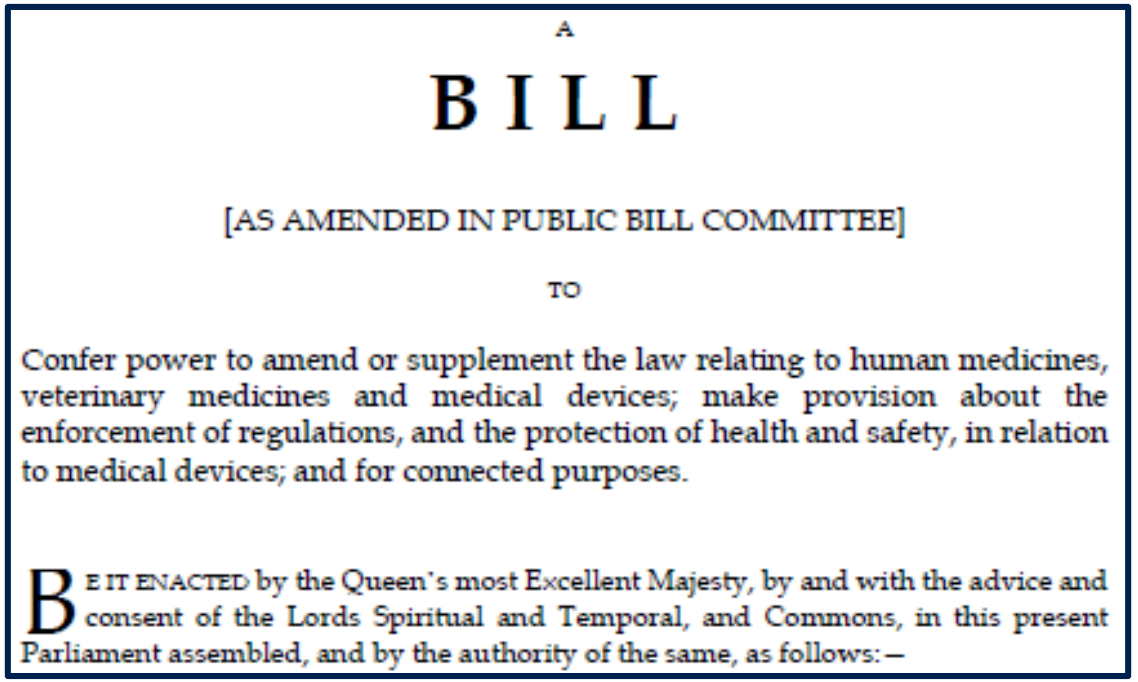


New UK regulations

1. Medicines and Medical Devices Bill

Confers power to the minister.

Changes to simplify enforcement (includes new civil sanctions).



A

BILL

[AS AMENDED IN PUBLIC BILL COMMITTEE]

TO

Confer power to amend or supplement the law relating to human medicines, veterinary medicines and medical devices; make provision about the enforcement of regulations, and the protection of health and safety, in relation to medical devices; and for connected purposes.

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

2. Medical device regulations

Looking to EU MDR/IMDRF/FDA/TGA/… for best regulatory practice.

- keep a register of all devices approved for the UK market
- Manufacturers should be required to apply to the MHRA before marketing their device.
- MHRA should assess the application in a way that is proportionate to the risks posed taking into account relevant factors such as, the evidence base supplied, approvals in other jurisdictions, and the post-marketing surveillance plans.
- Given there are an estimated 600,000 or more devices on the market we recognise that initially this will almost certainly involve some ‘grandfathering’ of currently marketed devices

Update on delay to full implementation

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The European Parliament and Council have approved a proposal to delay the full implementation of the Medical Device Regulation 2017/745 (MDR) for one year to 26 May 2021. This means that the full applicability of the MDR will fall outside of the transition period agreed with the EU.

We are taking steps to plan for after the end of the transition period. We will provide guidance on this in due course in light of Government decisions required on the future of UK regulation. All decisions on regulations will be taken with a view to prioritising patient safety and ensuring patient access for medical devices.

In the meantime, the existing regulatory requirements should continue to be met.”

Questions

Links:

MDCG Guidance (significant change/cyber/clinical evidence):

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

New UK Medicines and Medical devices Bill

https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices/documents.html

Software Guidance:

https://www.gov.uk/government/publications/medical-devices-software-applications-apps

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MHRA

Thank you

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