UK medical device regulatory changes

The recently published ”Government response to consultation on the future regulation of medical devices in the United Kingdom” has given us some insight into the UK Government’s intentions for the new UK Regulatory Framework due to be released in 2023.

What is changing?

- A phased approach to transitional arrangements has been signalled with the conformity deadline of 1 Jul 2023 being extended under certain conditions as detailed below.
- Closer alignment with EU MDR / IVDR (2017) requirements in certain areas with some UK specific requirements.

What is not changing?

- Current requirement that manufacturers and devices must be registered with the MHRA.
- Current requirements for manufacturers from outside the UK to appoint a UK Responsible Person.
- Urgency in preparation for the forthcoming regulatory changes to avoid delays and market barriers. This includes changes from EU MDD / IVDD to MDR / IVDR which will provide a better transitional arrangement under the UK regulations.

This is the first part in a planned series of summarised elements from the aforementioned 155 page publication.

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Transitional arrangements

Transitional arrangements which will allow, at a minimum, products to be placed on the market until either the CE certificate expires, or for three years after the new regulations take effect (in the case of general medical devices) or five years (in the case of IVDs), whichever is sooner.
The caveats that will apply to this arrangement are:

- Devices that are subject to significant changes in design or intended purpose will be excluded from these provisions
- All post-market requirements applicable to the new regulatory framework will need to be complied with for all products which benefit from the transitionary arrangements

Transitional arrangements for CE Marked devices

General Medical devices and IVDs with a CE certificate under **MDR or IVDR** may continue to be placed on the market until either the certificate expires, or for ***five years*** after the new regulations take effect, whichever is sooner. This will apply even if the certification / declaration of conformity is dated after the new regulations take effect. Products certified to this regulation will be permitted to be placed on the Great Britain market for up to five years from the date on which the new regulatory framework takes effect.

General Medical devices and In Vitro Diagnostics (IVDs) with a CE certificate under ***MDD or IVDD*** may, at a minimum, be placed on the market until either the certificate expires or for ***three years (for general medical devices)*** and ***five years (for IVDs)*** after the new regulations take effect, whichever is sooner.
The caveats that will apply to both categories of CE Marked devices covered by these arrangements are:

- Devices that are subject to significant changes in design or intended purpose will be excluded from these provisions
- All post-market requirements applicable to the new regulatory framework must be

complied with for all products which benefit from the transitionary arrangements

Transitional arrangements for clinical investigations

Any clinical investigations that commence under the existing regulations before the new regulations take effect, and which would not be completed before the new regulations take effect, may continue without a requirement to re-apply to the MHRA, on the proviso that the clinical investigation complies with all reporting requirements set out in the new regulations.