UK Medical Device Regulatory changes:- Post-Market Surveillance, Vigilance and Market Surveillance

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.

We continue our summary of sections from the UK Government’s response with a look at the impact the intended changes to Post-market Surveillance, Vigilance and Market Surveillance.

Post-Market Surveillance

The UK Government has indicated that stronger requirements are to be introduced for manufacturers to implement a post-market surveillance system. Alignment with EU regulations was seen as being of benefit economically and operationally. The regulations will outline what should be included in post-market clinical follow up (PMCF – for medical devices) and post-market performance follow up (PMPF – for IVDs) and the level of detail required shall be risk based.

Further details of the legislation has not been made available at this time but there is a commitment to provide clear guidance to augment the legislation.

Reporting of serious incidents and field safety corrective actions (FSCA)

The new regulations are to include definitions of ‘serious incident’, ‘serious deterioration’ and ‘serious public health threat’. These definitions will be closely aligned to those set out in the EU regulations but not identical.

The definition of serious incident will be changed from “the permanent or temporary serious deterioration of a patient’s, user’s or other person’s state of health” to “serious deterioration of any person’s state of health”. The terms “permanent and temporary” are superseded by a definition of “serious deterioration”.

Mental health impacts will not be included in serious incident reporting at this stage due to appropriate mechanisms not being in place, but the UK Government acknowledge their seriousness. This important issue will be kept under review.

Trend reporting

Manufacturers will be required to report statistically significant data as follows:

- for general medical devices and IVDs - any statistically significant increase in the frequency or severity of incidents that could have a significant impact on the benefit-risk analysis;
- for IVDs - any significant increase in expected erroneous results established in comparison to the stated performance of the IVD or respective assays.

Recognising that this may prove disproportionate for low volume devices, the UK Government has committed to consider this further and provide additional guidance and wider policy development.

Analysis of serious incidents and field safety corrective actions (FSCA)

Manufacturers will be required to issue field safety notices (FSN) and minimum requirements for content will be regulated.

Submission of the content to the Medicines & Healthcare products Regulatory Agency (MHRA) for comment will not be required, at this time as the systems are not in place to support it.

The MHRA will be required to notify the manufacturer and UK Responsible Person of new risks it has identified through active monitoring of data.

A proposal to mandate patient and public involvement as part of vigilance obligations will not be introduced. However, guidance will be provided to manufacturers on engaging with patients and the public as part of vigilance obligations based on risks and intended use.