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UK PMS GUIDANCE SUMMARY

OVERVIEW

Last week the UK released a new draft guidance outlining requirements for post-market surveillance. The guidance is open for comment for the next 60 days, and is expected to be finalized this winter. Its entry into full effect is targeted for mid-2024.

DETAILED REQUIREMENTS

- Manufacturers must maintain a PMS system for each device on market or in service that is proportionate to risk of the device and includes device-related data.
- Manufacturers must take preventive and/or corrective actions when risks that compromise safety or performance are identified, or if the device is identified as out of conformance with the essential requirements. Manufacturers will notify the appropriate party of the actions taken.
- In most cases, serious incidents must be reported to the Secretary of State immediately after the manufacturer has established the causal or reasonably possible causal relationship between the device and the serious incident no later than 15 days after the manufacturer becomes aware of the incident.
- If the serious incident involves a serious public health threat, the report must be submitted no later than 2 days after the manufacturer becomes aware of the threat.
- If there is a death or an unanticipated serious deterioration to a patient, the report must be submitted no later than 10 days after the manufacturer becomes aware of the incident.
- Manufacturers of devices on market or in service in Great Britain must report field safety corrective actions (FSCA) outside Great Britain if the FSCA relates to a device which is of the same type as the device in Great Britain and the manufacturer is not taking the same FSCA in Great Britain.
- Class I or In Vitro A and B devices will require a post market surveillance report that summarizes the manufacturer's conclusions and analyses of the PMS plan data. The report must also include summaries of any preventive or corrective actions. PMS plans will be produced within 3 years of market or service entry and updated every 3 years throughout the PMS period. The draft outlines any exceptions to this requirement.
- Manufacturers must produce periodic safety update reports (PSUR) for devices that are exempt from PMS reporting. The PSURs must be produced within 2 years of market or service entry for Class IIa devices and updated every 2 years, or within 1 year of market or service entry, and update the PSUR yearly throughout the PMS period for higher device classifications.

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DETAILED REQUIREMENTS, CONT.

- Manufacturers must report significant increases in the frequency or severity of incidents involving a device if the increase could have a significant adverse impact. Manufacturers must also report increases in expected erroneous results in comparison to the stated performance of the device in the instructions for use (IFU).
- If the Secretary of State notifies a manufacturer about a reported incident, the manufacturer must consider whether the incident is serious and requires action. If the manufacturer determines no action is needed, they must provide an explanatory statement to the Secretary of State. If the Secretary of State does not agree, the manufacturer must take action as if the incident is considered a serious incident.
- If the Secretary of State notifies a manufacturer of an identified risk or safety concern, the manufacturer must investigate the concern and submit a report to the Secretary of State as soon as possible.
- PMS documentation must be maintained for whichever is longer: the PMS period of the device model and 15 years in the case of an implantable device, or 10 years in the case of any other device.
- The manufacturer and the UK responsible person must provide any reports to the Secretary of State upon request and within 3 working days of the request.

COMPARISON TO EU MDR

Overall the two sets of requirements are very similar. However, EU MDR requires records be kept for 10 years minimum after a device is last marketed, or 15 years minimum for implantable devices. The UK draft states records should be kept for the device's full post-market surveillance period plus 10 or 15 years depending on device type. Since the surveillance period runs through a device's entire lifetime, the UK retention timeframe could end up being longer.

STAY AHEAD OF THE CURVE

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