ARTHUR COX

New Medical Device Regulations

Knowledge Bites: Part 4

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Post market surveillance will now require periodic updates

The new EU Medical Device Regulations, which are due to be voted on by the European Parliament, will result in increased post market surveillance and vigilance requirements for medical device manufacturers. One of the new requirements in the field of vigilance reporting is the periodic safety update report (**PSUR**).

Manufacturers of class IIa, IIb and III devices along with manufacturers of class C and D IVD devices will now need to complete and maintain a PSUR for each device or category/group of devices that they manufacture. Companies must now be prepared to update their technical file to include PSURs.

INFORMATION TO BE INCLUDED IN THE PSUR

Similar to the PSUR for medicinal products, these reports will summarise post-market surveillance data and describe any preventive and corrective actions taken during that period in relation to the device(s). For instance, the PSUR must include information on:

» the benefit-risk analysis for the devices;

» the main findings of the post-market clinical follow-up;

» the volume of sales of devices;

» an estimate of the size and other characteristics of the population using the device; and

» where practicable, the usage frequency of the device.

FREQUENCY AND SUBMISSION PROCEDURE

CLASS OF DEVICE	FREQUENCY	METHOD OF SUBMISSION
Class IIa	At least every 2 years and earlier if necessary	Make available to notified bodies and, on request, to competent authorities
Class IIb	Annually	Make available to notified bodies and, on request, to competent authorities
Class III	Annually	Upload onto Eudamed
Class C IVD	Annually	Make available to notified bodies and, on request, to competent authorities
Class D IVD	Annually	Upload onto Eudamed

NEW ELECTRONIC DATABASE

For class IIa, IIb and class C IVD devices, manufacturers only have to make the PSUR available to notified bodies and, on request, to competent authorities. However, for higher risk devices such as class III and Class D IVD devices, manufacturers will be required to proactively submit a PSUR to notified bodies by means of a newly created electronic system which will sit within Eudamed. For these devices, the notified body will review the PSUR and add its own evaluation to that electronic system with details of any action taken. The PSUR and the notified body evaluation will also be made available to competent authorities and the European Commission through that database. The database will be set up, maintained and managed by the European Commission in consultation with the Medical Device Coordination Group. The detailed arrangements in terms of establishing and maintaining the electronic database will be revealed by means of implementing acts adopted by the European Commission.

For further information on the new medical device regulations, see our other briefings in this series:

Knowledge Bites, Part 1: Unnanounced audits

Knowledge Bites, Part 2: Supply chain division of responsibility

Knowledge Bites, Part 3: How does the new scrutiny procedure look?

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