Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Section 1

Post-market surveillance

Article 78

Post-market surveillance system of the manufacturer

1 For each device manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(8).

2 The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3 Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

a to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

b to update the design and manufacturing information, the instructions for use and the labelling;

c to update the performance evaluation;

d to update the summary of safety and performance referred to in Article 29;

e for the identification of needs for preventive, corrective or field safety corrective action;

f for the identification of options to improve the usability, performance and safety of the device;

g when relevant, to contribute to the post-market surveillance of other devices; and

h to detect and report trends in accordance with Article 83.

The technical documentation shall be updated accordingly.

4 If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 82.

Article 79

Post-market surveillance plan

The post-market surveillance system referred to in Article 78 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1 of Annex III. The post-market surveillance plan shall be part of the technical documentation specified in Annex II.

Article 80

Post-market surveillance report

Manufacturers of class A and B devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the notified body and the competent authority upon request.

Article 81

Periodic safety update report

1 Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

a the conclusions of the benefit-risk determination;

b the main findings of the PMPF; and

c the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of class C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified in Annexes II and III.

2 Manufacturers of class D devices shall submit PSUR by means of the electronic system referred to in Article 87 to the notified body involved in the conformity assessment of such devices in accordance with Article 48. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSUR and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3 For class C devices, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.