

Regulation (EU) 2017/745 of the European Parliament and of the Council
of 5 April 2017 on medical devices, amending Directive 2001/83/EC,
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing
Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

SECTION 2

Vigilance

Article 88

Trend reporting

1 Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in Article 84.

2 The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

Status:

Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 88.