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 87

Reporting of serious incidents and field safety corrective actions

1 Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

a any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

b any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.

2 As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3 Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 15 days after they become aware of the incident.

4 Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5 Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6 Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7 If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8 Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

9 For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10 The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11 Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 89.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting in accordance with Article 88, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.

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 **[**X1referred to in Sections 1 and 8 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.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 117 of 5 May 2017).

Article 89

Analysis of serious incidents and field safety corrective actions

1 Following the reporting of a serious incident pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.

The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2 Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3 In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the

device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

Upon request by the national competent authority, manufacturers shall provide all documents necessary for the risk assessment.

4 The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5 The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 92. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6 In the case of devices referred to in the first subparagraph of Article 1(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, inform the national competent authority or the EMA, depending on which issued the scientific opinion on that substance under Article 52(9), of that serious incident or field safety corrective action.

In the case of devices covered by this Regulation in accordance with point (g) of Article 1(6) and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, and in the case of devices falling under this Regulation pursuant to Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for human tissues and cells that was consulted by the notified body in accordance with Article 52(10).

7 After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.

8 The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow it to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular, by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for

patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

The manufacturer shall enter the field safety notice in the electronic system referred to in Article 92 through which that notice shall be accessible to the public.

9 The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

a where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

b where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

That coordinated procedure shall cover the following:

— designation of a coordinating competent authority on a case by case basis, when required;

— defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority and the involvement of other competent authorities.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

The coordinating competent authority shall, through the electronic system referred to in Article 92, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10 The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11 The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 90

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 92, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

Article 91

Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 85 to 90 and 92 as regards the following:

(a) the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 85, 86, 87, 88 and 89 respectively;

(c) standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 87;

(e) harmonised forms for the exchange of information between competent authorities as referred to in Article 89;

(f) procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 92

Electronic system on vigilance and on post-market surveillance

1 The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

a the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87(1) and Article 89(5);

b the periodic summary reports by manufacturers referred to in Article 87(9);

c the reports by manufacturers on trends referred to in Article 88;

d the PSURs referred to in Article 86;

e the field safety notices by manufacturers referred to in Article 89(8);

f the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 89(7) and (9).

That electronic system shall include relevant links to the UDI database.

2 The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 53.

3 The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4 On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5 The reports on serious incidents referred to in point (a) of Article 87(1) shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6 The trend reports referred to in Article 88(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member State in which the incidents occurred.

7 The reports on field safety corrective actions referred to in point (b) of Article 87(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

a the Member States in which the field safety corrective action is being or is to be undertaken;

b the Member State in which the manufacturer has its registered place of business.

8 The periodic summary reports referred to in Article 87(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

a the Member State or Member States participating in the coordination procedure in accordance with Article 89(9) and which have agreed on the periodic summary report;

b the Member State in which the manufacturer has its registered place of business.

9 The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 56.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, SECTION 2.