

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.

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

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.

Status: Point in time view as at 05/04/2017.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)*

Section 2

Vigilance

Article 82

Reporting of serious incidents and field safety corrective actions

1 Manufacturers of devices, made available on the Union market, other than devices for performance study, shall report, to the relevant competent authorities, in accordance with Articles 87(5) and (7), the following:

- a any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 83;
- 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 87.

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) immediately after they have established a 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.

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

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 84(9), in consultation with the competent authorities referred to in points (a) and (b) of Article 87(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 87(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 84.

Where the manufacturer of the device concerned considers that the incident is not a serious incident or is to be treated as an increase in expected erroneous results, which will be covered by trend reporting in accordance with to Article 83, 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 84.

Article 83

Trend reporting

1 Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents 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 unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in points (a) and (b) of Section 9.1 of Annex I and 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 events or change in performance, as well as the observation period, in the post-market surveillance plan referred to in Article 79.

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

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.

Article 84

Analysis of serious incidents and field safety corrective actions

1 Following the reporting of a serious incident pursuant to Article 82(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include risk assessment of the incident and field safety corrective action taking into account the 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 82 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 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 the 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 for 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 87. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6 In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, depending on whether the relevant competent authority of the Member State that authorised the medicinal products or the EMA was consulted by the notified body in accordance with the procedures set

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

out in Section 5.2 of Annex IX and Section 3.11 of Annex X, inform that national competent authority or the EMA, as appropriate.

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 87, 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 serious incidents 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 them 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 87 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 87, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

Status: Point in time view as at 05/04/2017.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)*

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 85

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 87, 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 86

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 80 to 85 and 87 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 80, 81, 82, 83 and 84 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 82;
- (e) harmonised forms for the exchange of information between competent authorities as referred to in Article 84;
- (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.

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 87

Electronic system on vigilance and 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 reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 82(1) and Article 84(5);
- b the periodic summary reports by manufacturers referred to in Article 82(9);
- c the reports by manufacturers on trends referred to in Article 83;
- d the PSURs referred to in Article 81;
- e the field safety notices by manufacturers referred to in Article 84(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 84(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 49.

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 82(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 83(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 States in which the incidents occurred.

7 The reports on field safety corrective actions referred to in point (b) of Article 82(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 State 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 82(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

Status: Point in time view as at 05/04/2017.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)*

- a the Member State or Member States participating in the coordination procedure in accordance with Article 84(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 51.

Section 3

Market surveillance

Article 88

Market surveillance activities

1 The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2 The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 99 and local circumstances.

3 In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

- a may require economic operators to, *inter alia*, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and
- b shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4 The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 95.

5 The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6 Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7 The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the final report, the competent authority shall

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 95.

8 The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 95.

9 The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

10 Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11 Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

- (a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or
- (b) otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device.

The relevant economic operators shall cooperate with the competent authorities.

Article 90

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1 Where, having performed an evaluation pursuant to Article 89, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2 The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 51 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 95.

3 The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4 Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 95.

5 The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6 Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 95, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 95.

7 Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified. In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

Article 91

Procedure for evaluating national measures at Union level

1 Where, within two months of receipt of the notification referred to in Article 90(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2 Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 90(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 90(4), the national measure shall be considered to be justified.

3 Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 92

Other non-compliance

1 Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2 Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall without delay take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 95.

3 In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 93

Preventive health protection measures

1 Where a Member State, after having performed an evaluation, which indicates a potential risk related to a device or a specific category or group of devices considers that, in

Status: Point in time view as at 05/04/2017.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)

order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2 The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 95.

3 The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

4 Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts) to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 94

Good administrative practice

1 Any measure adopted by the competent authorities of the Member States pursuant to Articles 90 to 93 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2 Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3 Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

4 Where a measure adopted pursuant to Articles 90 to 93 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall

Status: Point in time view as at 05/04/2017.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII. (See end of Document for details)*

by means of the electronic system referred to in Article 95 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

Article 95

Electronic system on market surveillance

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

- a summaries of the results of the surveillance activities referred to in Article 88(4);
- b the final inspection report as referred to in Article 88(7);
- c information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 90(2), (4) and (6);
- d information in relation to non-compliance of products as referred to in Article 92(2);
- e information in relation to the preventive health protection measures referred to in Article 93(2);
- f summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in Article 88(8).

2 The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 51 for the device concerned and be accessible to the Member States and to the Commission.

3 Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

Status:

Point in time view as at 05/04/2017.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER VII.