~~*1a. Trend reports on anticipated side-effects leading to serious incidents shall be automatically transmitted by the electronic system to the concerned member states. The provisions of article 63 shall apply.*~~

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

~~*2. Manufacturers of implantable devices and devices falling within class III shall submit, by means of the electronic system referred to in Article 66a, periodic safety update reports including:*~~

~~*(a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certificate and the vigilance summary referred to in Article 61 (1);*~~

~~*(b) a scientific evaluation of the risk-benefit ratio of the device;*~~

~~*(c) all data relating to the volume of sales of the devices including an estimate of the population exposed to the device.*~~

~~*Manufacturers shall submit safety update reports annually during the period of validity of the first certificate. In case of certificate renewal, these reports shall be transmitted every two years.*~~

~~*Article 65* **61b**~~

~~***Updating technical** Documentation **based on** of vigilance data~~

~~Manufacturers shall update their technical documentation **listed in Annex IIa** with **vigilance data**:~~

~~**(a)** information on incidents received from **competent authorities**, healthcare professionals, patients, and users, **and any other economic operators;**~~

~~**(b)** **reports on** serious incidents, field safety corrective actions, **and** periodic summary reports referred to in Article 61 **and trend reports referred to in article 61a**,~~

~~**(c)** trend reports referred to in Article 64 and field safety notices referred to in Article 63(5).~~

~~They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

~~*Article 83* **61c**~~

~~*Device registers*~~

~~The Commission and the Member States shall take all appropriate measures to encourage the establishment of **and co-operation and interoperability between** registers for specific types of devices to gather post-market experience related to the use of such devices **in a systematic manner**. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices~~

~~***Article 61d***~~

~~***Manufacturers' obligation to cooperate with the competent authorities as regards risk evaluation***~~

~~***1. The manufacturer shall conduct without delay all investigations necessary to assess the risk of any device in respect of which a serious incident was reported to him or a field safety corrective action was taken and inform the competent authorities of the Member States where the incident occurred about the outcome. However, the manufacturer shall consult the competent authority before performing 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.***~~

~~*1a. The manufacturer shall provide a final report about its findings, by means of the electronic system referred to in Article 66a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.*~~

~~*2. Upon request by a competent authority, the manufacturer shall provide all documents necessary for a risk evaluation, particularly relevant parts of the risk analysis and the clinical evaluation for the device concerned by electronic means.*~~

~~*Article 62*~~

~~*Electronic system on vigilance*~~

~~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 61(1);~~

~~(b) the periodic summary reports by manufacturers referred to in Article 61(2);~~

~~(c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);~~

~~(d) the reports by manufacturers on trends referred to in Article 64;~~

~~(e) the field safety notices by manufacturers referred to in Article 63(5);~~

~~(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).~~

~~2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.~~

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

~~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 database 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 and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on serious incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:~~

~~(a) the Member State where the incident occurred;~~

~~(b) the Member State where the field safety corrective action is being or is to be undertaken;~~

~~(c) the Member State where the manufacturer has his registered place of business;~~

~~(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.~~

Article 63

Analysis of serious incidents and field safety corrective actions

0. ***Following the reporting of a serious incident pursuant to Article 61, paragraph 1, the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2 as appropriate.***

The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body during these investigations 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.

1. 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 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer***, and, where relevant, with the notified body concerned***.

~~If, in the case of reports received in accordance with Article 61(3), the competent authority ascertains that the reports relate to a serious incident, it shall notify without delay those reports to the electronic system referred to in Article *66a* 62, unless the same incident has already been reported by the manufacturer.~~

2. ~~The~~ ***In the context of the evaluation referred to in paragraph 10 , the*** national competent ~~authorities~~ ***authority*** shall***, in cooperation with the manufacturers and where relevant the notified bodies body concerned, evaluate assess the risks arising from*** ~~carry out a risk assessment with regard to~~ ***the*** reported serious incidents ***and*** ~~or~~ field safety corrective actions, taking into account ***the protection of public health and*** the 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 and severity of ***that*** harm, clinical benefit of the device, intended and potential users, and population affected. ~~They~~ ***It*** 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 laid down in Annex I (xx)***.

~~On~~ Upon request by the national competent authority, the manufacturer shall provide ~~for a [preliminary] risk assessment and/or provide~~ all documents necessary for the risk assessment.

2a. ~~They~~ ***The national competent authority*** ~~***authorities,***~~ shall monitor the manufacturer's investigation of ~~the~~ ***a serious*** incident. ***Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.***

2b. ***The manufacturer shall provide a final report setting out its findings by means of the electronic system referred to in Article 66a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.***

3. In the case of devices referred to in the first subparagraph of Article 1(4) 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 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the second subparagraph of Article 42(2).

   In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the serious incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

4. After carrying out the ~~assessment~~ ***evaluation***, the evaluating competent authority shall, through the electronic system referred to in Article ***66a*** ~~62~~, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment. ~~***In all other cases, the evaluating competent authority shall provide to the manufacturer and, where applicable, to the reporting users and to the electronic system referred to in Article 66a, a final report on the outcome of its assessment.***~~

5. The manufacturer shall ensure that ~~the users of the device in question are informed without delay of~~ ***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 ~~***in an official Union language which can be easily understood by the affected user or patient***~~. ***The field safety notice shall be edited in*** ~~***the***~~ ***an official Union language or languages determined by*** ~~***in one of the official languages of***~~ ***the Member State where the field safety corrective action is taken*** ~~***or in another language which the Member State has indicated that it can accept.***~~ Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 6 of this Article, 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, in particular,***~~

~~***(a) identify the affected device, indicating the following elements: type of device, model name and number, batch/lot or serial numbers and part or order number,***~~

~~***(b) describe the deficiencies or malfunctions as well as, where identified, their causes;***~~

~~***(c) describe the product's risks and the facts on which the risk assessment is based,***~~

~~***(d) clearly explain the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person***~~

~~***(e) clearly indicate the necessary corrective measures,***~~

~~***(f) indicate a contact person or a contact point for further questions;***~~

~~***(g) indicate any additional useful information.***~~

The field safety notice shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.

~~*The manufacturer shall omit any comments or description that attempt to play down the level of risk in an inappropriate manner.*~~

The manufacturer shall enter the field safety notice in the electronic system referred to in Article ~~62~~ ***66a*** through which that notice shall be accessible to the public.

6. The competent authorities shall ~~designate~~ ***nominate*** a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:
   (a) where ***there is concern regarding a particular*** ~~similar~~ serious ***incident or cluster of serious*** incidents related to the same device or type of device of the same manufacturer ~~occur~~ in more than one Member State;
   (b) where the ***appropriateness of a*** field safety corrective action ***that is proposed by a manufacturer*** ~~*is in question* is being or is to be undertaken~~ in more than one Member State ***is in question***.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be ~~the one of~~ the Member State where the manufacturer ***or the authorised representative*** has his registered place of business.

The competent authorities shall actively participate in a coordination procedure ~~*developed by the MDCG*~~***. This procedure shall*** ~~*should*~~ ***include the following:***

- ~~*the*~~ ***designation of a coordinating authority on a case by case basis, when required;***
- ***a definition of the coordinated assessment process;***
- ***tasks and responsibilities of the coordinating authority and the involvement of other competent authorities*** ~~*in this process*~~***.***

The coordinating competent authority shall***, through the electronic system referred to in Article*** ~~*62*~~ ***66a,*** inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7. ~~The coordinating competent authority shall carry out the following tasks:~~

   ~~(a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;~~

   ~~(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the serious incident on the certificate;~~

   ~~(c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 62 *66a*(5) on the format, content and frequency of periodic summary reports in accordance with Article 61(2);~~

   ~~(d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;~~

   ~~(e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 62 *66a*, of the progress in and the outcome of its assessment.~~

   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.

8. The Commission shall provide ~~secretarial~~ ***~~logistical~~ administrative*** support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

~~*Article 64*~~

~~*Trend reporting*~~

~~Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit 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 when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.~~

~~*Article 65*~~

~~*Documentation of vigilance data*~~

~~Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 61, trend reports referred to in Article 64 and field safety notices referred to in Article 63(5). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

Article 65a

Analysis of vigilance data

The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 66a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.

When a previously unknown risks is identified or the ~~a~~ frequency~~'s increasing~~ of an anticipated risks ~~that~~ significantly and adversely changes the risk-benefit determination ~~ratio~~, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions ~~inform users in accordance with Article 63(5)~~.

Article 66

Implementing acts

The Commission may, by means of implementing acts, ***and after consultation of the MDCG,*** adopt the modalities and procedural aspects necessary for the implementation of Articles ~~61~~***d 63*** to 65***a and 66a*** as regards the following:

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

(b) ~~harmonised forms for~~ the reporting of serious incidents and field safety corrective actions, ***field safety notices,*** periodic summary reports, ***periodic safety update reports*** and trend reports by manufacturers as referred to in Articles ***60c,*** 61, ***61a*** and ***63*** ~~64~~;

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

(c) timelines for the reporting of ~~serious incidents and~~ field safety corrective actions, periodic summary reports, ~~and~~ trend reports ***and periodic safety update reports*** by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and ***60c*** ~~64~~;

(d) harmonised forms for the exchange of information between competent authorities as referred to in Article 63.

(e) procedures for designation of a coordinating competent authority; the coordinated assessment process; tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

*Article ~~62~~ **66a***

*Electronic system on vigilance ~~**Vigilance module in EUDAMED**~~*

1. The Commission shall, in collaboration with the Member States, ~~set up and manage an electronic system to~~ collate and process the following information ***by means of the electronic system set up pursuant to Article 27 including a link to the product information in accordance with article 24a ~~25.~~***:
   (a) the ~~***initial and final***~~ reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1) ***and Article 63 (~~12b~~)***;
   (b) the periodic summary reports by manufacturers referred to in Article 61(2);
   (c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);
   (d) the reports by manufacturers on trends referred to in Article ~~64~~ ***61a***;
   (da) the periodic safety update reports referred to in Article ~~61a~~ 60c;
   (e) the field safety notices by manufacturers referred to in Article 63(5);
   (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies ***that issued a certificate for the device in question in accordance with Article 43***.

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

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 database 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 ~~and field safety corrective actions~~ referred to in points (a) ~~and (b)~~ of Article 61(1)~~, the periodic summary reports referred to in Article 61(2),~~ ***and*** the reports on serious incidents referred to in the second subparagraph of Article 63(~~1~~2) ~~and the trend reports referred to in Article 64~~***to (c) of paragraph 1*** shall be automatically transmitted, upon receipt, via ~~***through***~~ the electronic system, to the competent ~~authorities~~ ***authority*** of the ~~following~~ Member States~~:~~.

~~(a) the Member State~~ where the incident occurred~~;~~.

5a. Trend reports on anticipated side-effects leading to serious incidents referred to in points (a) of Article 61(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member State where the incidents occurred.

6. The reports on field safety corrective actions referred to in point (b) of Article 61(1) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:

(~~b~~***a***) the Member State where the field safety corrective action is being or is to be undertaken;

(~~c~~***b***) the Member State where the manufacturer ***or his authorised representative*** has his registered place of business;

~~(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.~~

7. The periodic summary reports referred to in Article 61(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:

(a) the Member State that agreed on the periodic summary report;

(b) the Member State where the manufacturer or his authorised representative has his registered place of business.

~~*5a.*~~*8 The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system ~~referred to in Article 62~~, to the notified body that issued the certificate for the device in question in accordance with Article 45.*

SECTION 2 – MARKET SURVEILLANCE

Article 67

Market surveillance activities ~~at national level~~

1. The competent authorities ~~*for medical devices*~~ shall perform appropriate checks on the ***conformity*** characteristics and performance of ~~*the*~~ devices ~~*with the applicable legal requirements,*~~ including, where appropriate, ~~*clinical evaluation,*~~ review of ~~*technical*~~ documentation and physical or laboratory checks on the basis of adequate samples. They shall, ***in particular,*** take account of ~~*(a)*~~ established principles regarding risk assessment and risk management, ~~*(b)*~~ vigilance data and ~~*(c)*~~ complaints.

1a. The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 80 and local circumstances.

1b. ~~The~~ ***For the purpose referred to in the ~~previous~~ paragraph1, the*** competent authorities ~~may, inter alia:~~

(a) ***may, inter alia*** require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where ~~necessary and~~ justified, ~~enter the premises of economic operators and take~~ ***provide*** the necessary samples of devices ***free of charge***.

(b) ***and shall ~~[/may]~~ carry out both announced and, if necessary for control purposes, unannounced inspections of the premises of economic operators ~~whose devices are intended to be made available on the Union market~~, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users. ~~To that purpose, they shall designate a sufficient number of competent inspectors~~.***

1c. ***The Competent Authorities shall prepare an annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 75b.***

1d. ***The competent authorities*** ~~They~~ may ***confiscate,*** destroy or otherwise render inoperable devices presenting a serious risk ***or falsified products*** where they deem it necessary ***in the interest of the protection of public health***.

2. The Member States shall ~~periodically~~ review and assess the functioning of their 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. The Member State concerned shall make a summary of the results accessible to the public ***by means of the electronic system referred to in Article 75b***.

3. 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, ~~*by means of the electronic system referred to in Article 75b*~~ ***to provide for a harmonized 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.

4. 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.

5. ~~The~~ ***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.

~~*Without prejudice to any agreements between the EU and third countries, the inspections referred to in paragraph 1a may also take place in the premises established in a third country where the medical device is intended to be made available on the EU market.*~~

~~*6. The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this article as regards the good practices for market surveillance, particularly for inspection.*~~
~~*Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*~~

~~*Article 68*~~

~~*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) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 70(2), (4) and (6);~~

~~(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);~~

~~(c) information in relation to formal non-compliance of products referred to in Article 73(2);~~

~~(d) information in relation to preventive health protection measures referred to in Article 74(2).~~

~~2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.~~

Article 69

*Evaluation regarding ~~suspected non-compliant~~ devices **suspected to** presenting **an unacceptable** risk **or non-compliance** ~~to health and safety at national level~~*

Where the ~~***Member State***~~ competent authorities of a Member State, based on ***data obtained by*** vigilance ***or market surveillance activities*** ~~data~~ or other information, have ~~sufficient~~ reason to believe that a device ***may*** presents ~~a~~***n unacceptable*** risk to the health or safety of patients, users or other persons, ***or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation,*** they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by ***or non-compliance of*** the device. The relevant economic operators shall cooperate ~~as necessary~~ with the competent authorities.

Article 70

*Procedure for dealing with ~~non-compliant~~ devices presenting **an unacceptable** risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device ~~***according to that evaluation***, which~~ presents a***n unacceptable*** risk to the health or safety of patients, users or other persons, ***or to other aspects of the protection of public health and*** ~~does not comply with the requirements laid down in this Regulation~~, they shall without delay require the ***manufacturer of the devices concerned, his authorised representatives and all other*** relevant economic operator***s*** to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to ~~prohibit or~~ 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, proportionate to the nature of the risk ***or non-compliance***. ~~***The Competent Authority of the Member State in which the manufacturer of the concerned device is located shall be informed.***~~

2. ***The*** ~~Where the~~ competent authorities ~~consider that non-compliance is not restricted to their national territory, they~~ shall ~~inform~~ ***notify*** the Commission***,*** ~~and~~ the other Member States ***and the notified body that issued a certificate in accordance with Article 45 for the device concerned*** 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 ***75b*** ~~68~~.

3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

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

   They shall notify the Commission***,*** ~~and~~ the other Member States ***and the notified body that issued a certificate in accordance with Article 45 for the device concerned***, without delay, of those measures, by means of the electronic system referred to in Article ***75b*** ~~68~~.

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 ~~***if available by means of the electronic system referred to in Article 25***~~, 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.