Any assessment as to whether there are grounds for refusal as referred to in Article 55 shall be carried out under the direction of the coordinating Member State.

5. For the purpose of Article 57(3), the sponsor shall submit the clinical investigation report to the Member States concerned by means of the electronic system referred to in Article 53.

6. The Commission shall provide secretarial support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

Article 59

Recording and reporting of events occurring during clinical investigations

1. The sponsor shall fully record any of the following:

(a) an adverse event identified in the clinical investigation plan as critical to the evaluation of the results of the clinical investigation in view of the purposes referred to in Article 50(1);

(b) a serious adverse event;

(c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report to all Member States where a clinical investigation is conducted without delay any of the following:

(a) a serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

(b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation.

4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to

in paragraph 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 58(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical investigation needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market clinical follow-up investigations referred to in Article 54(1), the provisions on vigilance contained in Articles 61 to 66 shall apply instead of this Article.

Article 60
Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter as regards the following:

(a) harmonised forms for the application for clinical investigations and their assessment as referred to in Articles 51 and 58, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 53;

(c) harmonised forms for the notification of post-market clinical follow-up investigations as referred to in Article 54(1), and of substantial modifications as referred to in Article 55;

(d) the exchange of information between Member States as referred to in Article 56;

(e) harmonised forms for the reporting of serious adverse events and device deficiencies as referred to in Article 59;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 59.

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

Chapter VII
Vigilance and market surveillance

SECTION 1 – VIGILANCE

Article 61
Reporting of incidents and field safety corrective actions

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:

   (a) any serious incident in respect of devices made available on the Union market;

   (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.

   Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.

   The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.

4. Manufacturers of custom-made devices shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

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

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.

   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 62, unless the same incident has already been reported by the manufacturer.

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They 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. They shall monitor the manufacturer's investigation of the incident.

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, the evaluating competent authority shall, through the electronic system referred to in Article 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.

5. The manufacturer shall ensure that the users of the device in question are informed without delay of the corrective action taken by means of a field safety notice. 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 manufacturer shall enter the field safety notice in the electronic system referred to in Article 62 through which that notice shall be accessible to the public.

6. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:

(a) where similar 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 field safety corrective action is being or is to be undertaken in more than one Member State.

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

The coordinating competent authority shall 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(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, 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 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 66
Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of Articles 61 to 65 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, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;

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

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

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

SECTION 2 – MARKET SURVEILLANCE

Article 67
Market surveillance activities

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may 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 the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.

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.

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. Where appropriate, the competent authorities of the Member States shall agree on work-sharing 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 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 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 devices presenting a risk to health and safety at national level

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, 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 the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Article 70

Procedure for dealing with non-compliant devices presenting a risk to health and safety

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator 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.

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States 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 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, without delay, of those measures, by means of the electronic system referred to in Article 68.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification 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 of any additional 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 68.

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 a provisional measure taken by a Member State, that measure shall be deemed justified.

8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.

Article 71
Procedure at Union level

1. Where, within two months of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall 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 88(3).

2. If the national measure is considered justified, Article 70(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. Where, in the situations referred to in Articles 70 and 72, a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) 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 88(3).

3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 88(4).

Article 72
Procedure for dealing with compliant devices presenting a risk to health and safety

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

2. The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 68. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.

3. The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

4. Where the national measure is considered justified, Article 70(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

Article 73
Formal non-compliance

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:

   (a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 18;

   (b) that the CE marking has not been affixed to a device contrary to Article 18;

(c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;

(d) that the EU declaration of conformity has not been drawn up or is not complete;

(e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete or not provided in the language(s) required;

(f) that the technical documentation, including the clinical evaluation, is not available or not complete.

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall 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 68.

Article 74
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 the making available on the market or putting into service of such device or 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 order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necessary and justified provisional measures.

2. The Member State 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 68.

3. The Commission shall assess the provisional national measures taken. The Commission shall decide, by means of implementing acts, whether the national measures are justified or not. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

4. Where the assessment referred to in paragraph 3 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 shall be empowered to adopt delegated acts in accordance with Article 89 to take the necessary and duly justified measures.

Where in this case imperative grounds of urgency so require, the procedure provided for in Article 90 shall apply to delegated acts adopted pursuant to this paragraph.

Article 75
Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 70 to 74 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of serious 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 before any measure is adopted. If action has been taken without the economic operator's being heard, he 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 he has taken effective corrective action.

4. Where a measure adopted pursuant to Articles 70 to 74 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall inform the relevant notified body of the measure taken.

Chapter VIII
Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Article 76
Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.

2. For the implementation of Articles 50 to 60, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.

Article 77
Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.

2. Member States and the Commission shall participate in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 78
Medical Device Coordination Group

1. A Medical Device Coordination Group (MDCG) is hereby established.

2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate providing expertise in the field of this Regulation, and one member and one alternate providing expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices]. A Member State may choose to appoint only one member and one alternate providing expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, on a request from the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of this Regulation, or by the members appointed for their expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices], or by the members appointed for both Regulations, as appropriate.

4. The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by the majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based are recorded in the MDCG's position.

5. The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

7. The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited in such sub-groups in the capacity of observers.

8. The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

– the adoption of opinions or recommendations or other positions by the MDCG, including in cases of urgency;

– the delegation of tasks to reporting and co-reporting members;

– the functioning of sub-groups.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission.

Article 79
Support by the Commission

The Commission shall support the functioning of the cooperation between national competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

Article 80
Tasks of the MDCG

The MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;

(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;

(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.

Article 81
European Union reference laboratories

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.

2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:

(a) to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;

(b) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

(c) to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;

(d) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;

(e) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(f) to contribute to the development of standards at international level;

(g) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.

3. EU reference laboratories shall satisfy the following criteria:

(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the medical devices for which they are designated;

(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) to have the necessary knowledge of international standards and best practices;

(d) to have an appropriate administrative organisation and structure;

(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks.

4. EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 for the following purposes:

(a) amending or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3.

(b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.

7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.

Article 82
Conflict of interests

1. Members of the MDCG and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. Upon request, the declaration of interests shall be accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. Experts and other third parties invited by the MDCG on a case-by-case basis shall be requested to declare their interests in the issue in question.

Article 83
Device registers

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers for specific types of devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Chapter IX
Confidentiality, data protection, funding, penalties

Article 84
Confidentiality

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on medical confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

   (a) personal data in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001;

   (b) commercial interests of a natural or legal person, including intellectual property rights;

   (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 85
Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 86
Levy of fees

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

Article 87
Penalties

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Chapter X
Final provisions

Article 88
Committee procedure

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

Article 89
Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or the Council.

Article 90
Urgency procedure for delegated acts

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 89. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

Article 91
Amendments to Directive 2001/83/EC

In Annex I of Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where a product is governed by this Directive in accordance with the second subparagraph of Article 1(4) or the second subparagraph of Article 1(5) of Regulation (EU) [.../...] on medical devices[55], the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation contained in the

[55] OJ L [...], [...], p. [...].