

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 ~~through~~ the electronic system referred to in Article 75b, ~~(a)~~* of any additional *relevant* information at their disposal relating to the non-compliance of the device concerned and *~~(b)~~* of any measures adopted by them in relation to the device concerned.

- ~~6a.~~ In the event of disagreement *of a Member State* with the *a* notified national measure *referred to in paragraph 4 or in point (b) of paragraph 6*, they *the Member State* shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article *75b 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 *any provisional* measures taken by a Member State, ~~that~~ *those* measures shall be deemed *to be* justified.

8. ~~All~~ *Where paragraph 7 applies, all* Member States shall ensure that appropriate restrictive *or prohibitive* measures, *withdrawing, recalling or limiting the availability of the device on their national market* are taken without delay in respect of the device concerned.

Article 71

Procedure for evaluating national measures at Union level

1. Where, within two months of receipt of the notification referred to in Article 70(4) ~~and point (b) of 70(6)~~, 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, *after consulting the MDCG, and the national concerned competent authorities and, where necessary, the concerned economic operators*, evaluate the national measure. On the basis of the results of that evaluation, the Commission ~~shall~~ *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 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.
In the absence of a Commission decision the national measures shall be considered to be justified.

- 2a. ~~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 2a in accordance with the procedure referred to in Article 88(4).~~

Article 72

Procedure for dealing with compliant devices presenting an unacceptable 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 ***previously unknown unacceptable*** risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall, ***if it considers that the risk-benefit ratio has deteriorated to such an extent that the risk has become unacceptable,*** require the relevant economic operator or operators to take all appropriate provisional measures ***corrective actions*** 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.~~
- 2a. 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.*
3. ~~The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall *may* 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.~~
In the absence of a Commission decision the national measures shall be considered to be justified.
5. *The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.*

Article 73

Formal non-compliance

1. **Where, having performed an evaluation pursuant to Article 69, ~~Without prejudice to Article 70, where 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 put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance. where it makes *at least* one of the following findings, *related to formal non-compliance*:~~**
 - (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 *in conformity with this Regulation and the requirements set out in Article 17 and Annex IV in particular* 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 *in conformity with this Regulation and the requirements set out in Annex I Section III in particular* complete or not provided in the language(s) required;~~
 - (f) ~~that the technical documentation, including the clinical evaluation, is not available or not complete *in conformity with this Regulation and the requirements set out in Article 59 and Annex XIII in particular*;~~
 - (g) ~~that a conformity assessment according to Article 42 has not been carried out.~~

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 75b 68.
3. ***The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).***

Article 74

Preventive health protection measures

1. Where a Member State, after having performed an evaluation, which indicates a potential ***previously unknown unacceptable*** risk related to a device or a specific category or group of devices considers that, ***in 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 ~~such a~~ ***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 ~~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 75b 68.

3. The Commission, *in consultation with the MDCG and, where necessary, the concerned economic operators*, shall assess the ~~provisional~~ national measures taken. The Commission shall *may* decide, by means of implementing acts, whether the national measures are justified or not. *In the absence of a Commission decision 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 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 *may* adopt delegated *implementing* acts in accordance with *the examination procedure referred to in Article 89 88(3)* 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 *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 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 *provisional* measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he 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 70 to 74 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall *by means of the electronic system referred to in Article 75b* inform the relevant notified body *and the authority responsible for the notified body* of the measure taken.

Article 75a

Hazard alerts

~~Competent authorities shall alert patients and health professionals within the territory of their Member States shall put in place appropriate mechanisms, in accordance with national law and administrative practice, with a view to ensuring that patients and health professionals within their territory are alerted within an adequate timeframe of hazards they have identified relating to any device so as to avoid any injury or other damage. Member States shall be free to decide on what they consider to be the most appropriate manner of complying with this article.~~

Article 75b 68

Electronic system on market surveillance ~~Market surveillance module in EUDAMED~~

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: ~~by means of the electronic system referred to in point (g) of Article 27(2)~~
 - (aa) ~~summaries of the results of the surveillance activities referred to in Article 67 69(1c);~~
 - (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);
 - (e) *summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in 67(2).*

2. The information mentioned in paragraph 1 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 45 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 when this may impair market surveillance activities and co-operation between Member States.*

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 names and contact details of* the competent authorities ~~responsible for the implementation of this Regulation~~ 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 which shall provide for the organisation of exchanges with each other of the information necessary to enable this Regulation to be applied uniformly.~~
2. Member States ~~shall with the support of~~ and the Commission shall participate, ~~where appropriate,~~ 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, *upon* 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, *or their alternates*, 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 implementation of Article 82 regarding conflict of interests;***
 - the functioning of sub-groups;
 - ***procedures for appointing and replacing the Chairman.***

~~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. ***It shall, in particular, provide for the organisation of exchanges of experience between the 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 *and investigations* by manufacturers, the assessment by notified bodies *and the vigilance activities*;
- (ca) to contribute to the to the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements provided in this Regulation and Regulation (EU) No [.../...] [on in vitro diagnostic medical devices] are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;*
- (cb) to contribute to the development of devices standards, of Common Specifications and of scientific guidelines on clinical investigation of certain devices in particular implantable and class III devices;*
- (d) to assist the competent authorities of the Member States in their coordination activities *in particular* in the fields of *classification and regulatory status of devices*, clinical investigations, vigilance and market surveillance *including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 67;*
- (e) to provide advice ~~and assist the Commission~~, *either on its own initiative or* at its request *of the Commission*, in ~~its~~ *the* 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 81a

Provision of scientific, technical and clinical opinion and advice

1. *The Commission shall, in consultation with the MDCG and in cooperation with the Joint Research Centre, make provision for expert panels and expert laboratories to be appointed for the clinical evaluation in relevant medical fields as referred to in Paragraph 5abis and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, under the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 5.*
2. *Expert panels and expert laboratories may be appointed in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.*

3. ***Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.***

The members of expert panels shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests which shall be made publicly available.

The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

4. ***The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the Official Journal of the European Union and on the Commission website or following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.***

- 4a. ***The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. This list shall be published on the Commission website.***

5. ***Expert laboratories may be appointed by the Commission, following consultation with the MDCG [~~and in cooperation with the Joint Research Centre~~], on the basis of their expertise in physico-chemical characterisation, microbiological/biological/biocompatibility, mechanical, electrical, electronic or non-clinical biological/toxicological testing of specific devices, categories or groups of devices. The Commission shall only appoint expert laboratories for which a Member State or the Joint Research Centre have submitted an application for designation.***
- 5a. ***Expert panels appointed for the clinical evaluation in relevant medical fields shall fulfil the task specified in Article 49(2a) and Section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable.***

6. *Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:*
- (a) to provide scientific, technical and clinical assistance to the Commission and MDCG in relation to the implementation of this Regulation;*
 - (b) to contribute to the development and maintenance of appropriate guidance and common specifications for clinical investigations, clinical evaluation and PMCF and for physico-chemical characterisation, microbiological/biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;*
 - (c) to develop and review best practices clinical evaluation guidance for the state of art performance of conformity assessment procedures with regard to clinical evaluation, physico-chemical characterisation, microbiological/biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;*
 - (d) to contribute to the development of standards at international level, ensuring that these reflect the state of the art;*
 - (e) to provide opinions in response to consultations by manufacturers in accordance with article 49(21a), notified bodies and Member States in accordance with paragraphs 7-9.*
 - (f) to provide early advice on the clinical evaluation to manufacturer regarding devices for implantable [and invasive devices] classified as class III which are listed in annex ~~XX~~; to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;*
7. *The Commission, [in cooperation with the Joint Research Centre], shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, among others, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation and with regard to physico-chemical characterisation, microbiological/biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing.*

8. When adopting its scientific opinion in accordance with paragraph 5abis, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by the majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 5abis and 7, ensuring consideration of aspects of confidentiality as set out in Article 84. The clinical evaluation guidance referred to in paragraph 6(c) shall be published following consultation with MDCG.

9. Manufacturers and Notified bodies may be subject to pay fees to the Joint Research Centre for the advice provided by expert panels and expert laboratories except if the procedure is initiated in accordance with Annex VIII Section 6.0(c) and the fees are exempted by the Commission. The structure and the level of fees shall be adopted by the Commission by means of implementing acts in accordance with the examination procedure referred to in Article 88(3), taking into account the objectives of the adequate implementation of this regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels.

10. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend or supplement the tasks of expert panels and expert laboratories referred to in paragraph 56.