

## COMMISSION DECISION

of 30 July 2013

setting up a Commission expert group on rare diseases and repealing Decision 2009/872/EC

(2013/C 219/04)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Whereas:

- (1) Under Article 168(2) of the Treaty on the Functioning of the European Union, Member States are required, in liaison with the Commission, to coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.
- (2) The Commission White Paper 'Together for Health: A strategic approach for the EU 2008-2013' <sup>(1)</sup> adopted by the Commission on 23 October 2007, developing the EU health strategy, identified rare diseases as a priority for action.
- (3) Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013) <sup>(2)</sup> while reiterating that health services are primarily the responsibility of Member States, stresses that cooperation at Community level can benefit both patients and health systems. According to Article 7(2) and to the Annex to that Decision, the actions in the field of generation and dissemination of health information and knowledge shall be implemented in close cooperation with Member States developing consultation mechanisms and participatory processes.
- (4) The European Commission adopted on 11 November 2008 a 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe's challenges' <sup>(3)</sup> and the Council adopted on 8 June 2009 a Recommendation on an action in the field of rare diseases <sup>(4)</sup>. Point 7 of

the Commission Communication recommended that the Commission should be assisted by a European Union Advisory Committee on Rare Diseases.

- (5) Accordingly, on 30 November 2009, by Decision 2009/872/EC, the Commission set up the European Union Committee of Experts on Rare Diseases <sup>(5)</sup>. The term of office of the members of the Committee expires on 26 July 2013.
- (6) The Communication from the President to the Commission of 10 November 2010 entitled 'Framework for Commission Expert Groups: Horizontal rules and public register' <sup>(6)</sup> (hereinafter, the 'the framework for Commission expert groups') sets out a revised set of rules for all Commission expert groups. The new framework aims at simplifying and clarifying provisions introduced by the previous framework on expert groups in 2005, increasing transparency, enhancing coordination, while reducing the administrative workload for services.
- (7) In the light of the valuable work which has been carried out by the Committee of Experts on Rare Diseases since 2009 and taking into account the framework for Commission expert groups, there is a continuing need for a group of experts in this area. The tasks and the structure of a group of experts on rare diseases should be defined in compliance with the horizontal rules set out in the framework for Commission expert groups.
- (8) The expert group on rare diseases should, at the request of the Commission, provide advice and expertise to the Commission in formulating and implementing the Union's activities in the field of rare diseases and foster exchanges of relevant experience, policies and practices between the Member States and the various parties involved.
- (9) This group should be composed of representatives of Member States, representatives of patients' organisations in the field of rare diseases, representatives of producers of products or services relevant for patients affected by rare diseases and representatives from associations of European health professionals and medical societies and individual experts in order to allow a wide representation of stakeholders and experts in the area of rare diseases.

<sup>(1)</sup> COM(2007) 630 final, 23.10.2007.

<sup>(2)</sup> OJ L 301, 20.11.2007, p. 3.

<sup>(3)</sup> COM(2008) 679 final, 11.11.2008.

<sup>(4)</sup> OJ C 151, 3.7.2009, p. 7.

<sup>(5)</sup> OJ L 315, 2.12.2009, p. 18.

<sup>(6)</sup> C(2010) 7649 final.

- (10) The expert group on rare diseases should not act as a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (11) Personal data should be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data <sup>(2)</sup>.
- (12) Commission Decision 2009/872/EC of 30 November 2009 establishing a European Union Committee of Experts on Rare Diseases should thereby be repealed,

HAS DECIDED AS FOLLOWS:

*Article 1*

**Establishment of the expert group**

The group of experts on rare diseases, hereinafter referred to as 'the expert group', is hereby set up.

*Article 2*

**Tasks of the expert group**

1. At the request of the Commission or the Commission services, the expert group shall carry out the following tasks in the field of rare diseases:
- assist the Commission in the drawing up of legal instruments and policy documents, including guidelines and recommendations;
  - advise the Commission in the implementation of Union actions and suggest improvements to the measures taken;
  - advise the Commission in the monitoring, evaluation and dissemination of the results of measures taken at Union and national level;
  - advise the Commission on international cooperation;
  - provide an overview on Union and national policies;
  - foster exchanges of relevant experience, policies and practices between the Member States and the various parties involved.
2. In order to carry out the tasks referred to in paragraph 1, the expert group may in particular at the request of the Commission or the Commission services submit opinions, recommendations and reports.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.

<sup>(2)</sup> OJ L 8, 12.1.2011, p. 1.

3. The tasks of the expert group shall not comprise issues covered by Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products <sup>(3)</sup> and issues that fall under the tasks of the Committee of Orphan Medicinal Products (COMP), set up by Article 4 of that Regulation, nor issues that fall under the tasks of the Pharmaceutical Committee, set up by Council Decision 75/320/EEC <sup>(4)</sup>.

*Article 3*

**Consultation**

The Commission may consult the expert group on any matters relating to rare diseases.

*Article 4*

**Membership — Appointment**

1. The expert group shall be composed of the following members:

- Member States' competent authorities;
- patients' organisations in the field of rare diseases;
- European associations of producers of products or service providers relevant for patients affected by rare diseases;
- European professional associations or scientific societies acting in the field of rare diseases;
- individuals appointed in a personal capacity as experts having public health or scientific expertise at Union level in the field of rare diseases.

2. Competent authorities of the EFTA States which are party to the European Economic Area Agreement may also be members of the group, at the request of the EFTA States concerned.

3. Members shall be appointed by the Director-General for Health and Consumers.

4. The members referred to in points (b), (c), (d) and (e) of paragraph 1 shall not be more than four for each point and be appointed from a list of suitable candidates established following publication of a call for expressions of interest. The call for expressions of interests shall specify the required qualifications and conditions to become member of the expert group.

5. The members referred to in point (e) of paragraph 1 shall be appointed in their personal capacity. They shall act independently and in the public interest.

6. The members referred to in paragraph 1(a) to (d) and paragraph 2 shall nominate representatives and alternates to replace the representative when absent or indisposed. Alternates shall be nominated in accordance with the same conditions as representatives. Alternates shall automatically replace any members who are absent or indisposed.

<sup>(3)</sup> OJ L 18, 22.1.2000, p. 1.

<sup>(4)</sup> OJ L 147, 9.6.1975, p. 23.

7. The Director-General for Health and Consumers may refuse a representative or an alternate proposed by an organisation if he or she does not meet the profile required in the call for expressions of interest referred to in paragraph 4. In such cases, the organisation concerned shall be asked to nominate another representative or alternate.

8. The term of office of members of the expert group shall be three years and may be renewed after having responded to a further call for expressions of interest.

9. A member's term of office shall come to an end before the expiry of the three-year period in case of resignation.

10. Members referred to in paragraph 1(b) to (e), or their representatives, may be excluded or replaced for the remainder of their term of office in any of the following cases:

- (a) permanent incapacity to attend the meetings;
- (b) incapacity to contribute effectively to the group's deliberations;
- (c) non-compliance with the conditions set out in Article 339 of the Treaty on the Functioning of the European Union;
- (d) subsequent non-compliance with the qualifications and conditions specified in the call for expression of interests as referred to in paragraph 4.

11. The Director-General for Health and Consumers may ask a member referred to in paragraph 1(b) to (d) to nominate another representative or another alternate in the cases referred to in paragraph 10.

12. Members whose term of office comes to an end before the expiry of the three-year period pursuant to paragraphs 8 and 9 may be replaced for the remaining period of their mandate.

13. The names of members and their representatives shall be published in the Register of Commission expert groups and other similar entities ('the Register') <sup>(1)</sup>. The names of Member States' authorities may be published in the Register.

14. Personal data shall be collected, processed and published in accordance with Regulation (EC) No 45/2001.

#### Article 5

##### Operation

1. The expert group shall be chaired by the Director in charge of the policy on rare diseases of the Commission. The Director may delegate chairmanship to another Commission official.

2. In agreement with the Commission, the expert group may set up subgroups to examine specific questions on the basis of terms of reference defined by the group. Such subgroups shall be disbanded as soon as their mandate is fulfilled.

<sup>(1)</sup> Members who do not wish to have their names disclosed may apply for derogation from this rule. The request not to disclose the name of a member of an expert group shall be considered justified whenever publication could endanger his or her security or integrity or unduly prejudice his or her privacy.

3. The Commission's representative may invite experts from outside the expert group with specific competence in a subject on the agenda to participate in the work of the group. In addition, the Commission's representative may give observer status to individuals or organisations, as defined in Rule 8(3) of the framework for Commission expert groups, and candidate countries.

4. Members of expert groups and their representatives and alternates, as well as invited experts and observers, shall comply with the obligations of professional secrecy laid down by the Treaties and their implementing rules, as well as with the Commission's rules on security regarding the protection of EU classified information, laid down in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom <sup>(2)</sup>. Should they fail to respect these obligations, the Commission may take all appropriate measures.

5. The meetings of the expert group and subgroups shall be held on Commission premises. The Commission shall provide secretarial services. The agenda and the minutes of the expert group's meetings shall be drawn up by the Commission. Other Commission officials with an interest in the proceedings may attend meetings of the expert group and its subgroups.

6. The expert group shall adopt its rules of procedure on the basis of the Commission standard rules of procedures for experts groups.

7. The Commission shall make available all relevant documents (such as agendas, minutes and participants' submissions) on the activities carried out by the expert group either by including it in the Register or via a link from the Register to a dedicated website, where information can be found. A document shall not be published where disclosure would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 <sup>(3)</sup>.

#### Article 6

##### Meeting expenses

1. Participants in the activities of the expert group shall not be remunerated for the services they render.

2. Travel and subsistence expenses incurred by participants in the activities of the expert group shall be reimbursed by the Commission in accordance with the provisions in force within the Commission.

3. The expenses referred to in paragraph 2 shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

<sup>(2)</sup> Commission Decision of 29 November 2001 amending its internal Rules of Procedure (OJ L 317, 3.12.2001, p. 1).

<sup>(3)</sup> These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

*Article 7*

**Repeal**

Decision 2009/872/EC is repealed.

*Article 8*

This Decision shall apply as from 27 July 2013.

Done at Brussels, 30 July 2013.

*For the Commission*  
Tonio BORG  
*Member of the Commission*

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