

## **Documents whose amendment is included in updated form**

Order	4330	23.08.2024	30.08.2024	
Order	2612	03.08.2023	07.08.2023	
Order	1609	14.06.2022	27.06.2022	

## **Ministry of Health**

### **ORDER No. 1.474\*)**

**of 5 August 2021**

**on establishment and operation of technical expert groups responsible for developing technical viewpoints on documents under debate at European level and ensuring representation at meetings of the working structures of EU institutions**

### **\*) Note:**

**Includes all changes made to the official document, published in the Official Gazette of Romania, mentioned in: Order of the Minister of Health no. 872/30.08.2024**

On seeing Approval Report no. IM 6.726 of 4.08.2021 of the Directorate for press relations, European affairs and international relations of the Ministry of Health,

Taking into account the provisions of Government Decision No. 34/2017 on the organisation and operation of the National System for the Management of European Affairs with a view to Romania's participation in the decision-making process of European Union institutions,

based on Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

**the Minister of Health hereby issues the following Order:**

**Art. 1** - (1) For the purposes of this Order, the terms below have the following meaning:

a) **SREAE** – the Foreign Relations and European Affairs Service;

- b) **MAE** – the Ministry of Foreign Affairs;
- c) **RP RO** - the Permanent Representation of Romania to the European Union in Brussels;
- d) **SM** – member states;
- e) **Negotiating mandate** - Romania's negotiating position for the topics on the agenda of the European Union Council, including for the legislative proposals of the European Commission or for those of another European Union member state in the areas of competence of the Ministry of Health. The mandate may contain, as appropriate, any limits/margins/alternatives which may be expressed in the negotiation process at the meetings.

If the economic, social or environmental implications of the European Commission's legislative proposals or other European initiatives are of major importance or if they concern several sectoral areas, the negotiating position will be adopted as a general mandate.

The position of the Ministry of Health on an issue which requires the development of a general mandate is approved by the minister/prime minister and follows the adoption procedure according to Government Decision No. 34/2017 on the organisation and operation of the National System for the Management of European Affairs with a view to Romania's participation in the decision-making process of European Union institutions;

f) **Mandate of representation** - the position of Romania's representation in the meetings of the working structures of European Union institutions;

g) **Travel report** - document drawn up following a business trip in order to provide information on the activities carried out during the trip. The travel report template is provided in Annex 4;

h) **Thematic file** - file on a specific field, which contains: Romania's mandates supported within the working groups/meetings at European level, the European documents which formed the basis for elaboration of the mandate, the working materials used within the meetings and copies of travel reports, as well as any positions of other MS transmitted, in order to continue the debates;

i) **Nomination proposal** - the report prepared by the specialised structure/competent authority/competent institution, addressed to the SREAE, proposing the participation of one or several experts in a working group/meeting at European level or the resolution of the manager of the specialised structure applied in writing to the original meeting agenda;

j) **Thematic file coordinator** - the appointed person who manages, monitors and transmits the mandate.

(2) The mandate is completed according to Annex 5 and must contain the following elements:

a) Negotiating mandate:

1. description - type of representation;
2. brief description of the subject on the agenda of the Council of the European Union or of the committees set up in accordance with the provisions 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;
3. relevance for Romania;
4. the economic, social and environmental impact on Romania in the case of draft legal documents of the European Union, as well as in the case of proposals for implementing binding legal acts of the European Union;
5. Romania's objectives in relation to the topic on the agenda of the Council of the European Union or of the committees established in line with the provisions of Regulation (EU) 182/2011;
6. positioning proposals;
7. the limits which can be accepted by Romania in the negotiation process;
8. following the topic (calendar, participation);
9. contextual elements;
- b) mandate of representation:
  1. description of the trip;
  2. description of the type of representation;
  3. structure of the delegation;
  4. mandate for discussions: brief description of the topic/topics on the agenda; relevance for Romania; Romania's objectives in relation to the topic on the agenda; positioning proposals; possible risks.

**Art. 2** - (1) The technical working groups are approved, consisting of experts responsible for developing technical viewpoints on documents under debate at European level and ensuring representation at meetings/working sessions of European Union institutions, which carry out their activity in specific areas, according to Annexes 1, 2 and 3 to this Order.

(2) For each work area, a technical working group is designated, consisting of experts who have responsibilities in developing Romania's position on the topics under discussion.

(3) One or several experts, designated by this Order, who are part of the technical working group for the working area(s), will ensure participation in the working groups of the Council of the European Union, as well as in the technical working groups formed by European Commission experts.

(4) Under duly justified conditions, the nomination proposal for participation in the technical working groups of the Council of the European Union, as well as in the technical working groups formed by European Commission experts, may include experts other than those mentioned in the Annexes to this Order. These experts may be from the Ministry of Health or from the structures/institutions subordinated/coordinated by the

Ministry of Health, as well as from other institutions with competences in the respective areas. In this case, the nomination proposal must include the motivation of the decision by the structure/institution making the proposal, be endorsed by the SREAE and approved by the Secretary General/Coordinating State Secretary of the respective area.

(5) Structures/institutions which make nominations for the amendment or supplementation of technical working groups formed by experts must request the SREAE to modify or supplement the technical working group whenever changes have occurred in its structure.

**Art. 3 -** (1) Approval for physical participation in European meetings/working groups is made by Order of the Minister of Health. For each participation in the meetings, the expert will request a travel order from the Ministry of Health.

(2) In the case of online participation in European meetings/working groups, the designation of experts is made by the Coordinators of the specialised departments and/or the Coordinators of the technical working groups formed by experts, depending on the area.

**Art. 4 -** The persons responsible for monitoring the technical working group of experts, established by this Order, are the following:

a) the secretary general or the secretary of state responsible for European affairs and international relations, according to the competences established by the Regulation on the organisation and operation of the Ministry of Health;

b) the Head of the SREAE;

c) the specialised staff within the European Affairs Department of SREAE, according to specific attributions.

**Art. 5 -** The experts mentioned in Art. 2 have the following duties:

a) in their field of expertise, drawing up the negotiating mandate relating to the documents under debate at the level of European institutions. The expert (group of experts) is (are) responsible for the correctness, quality and validity of the position expressed in the mandate, a position approved by the management of the specialised department or by the superior hierarchical leader (director/secretary of state/minister/prime minister), as the case may be. Negotiating mandates are endorsed by the SREAE and the SREAE Coordinator;

b) preparing the travel report provided for in Annex 4, within two working days after returning to their country of origin, if they represented Romania at meetings of the working structures of the European institutions or at other types of meetings; in the case of online meetings, they prepare the report provided for in Annex 4, within two working days after the meeting is over;

c) Participating in working groups and meetings at European level in their field of expertise;

- d) monitoring legislative developments at European level in their field of expertise and the positions of other Member States on the topics debated in the field;
- e) preparing the thematic file and updating it whenever necessary;
- f) informing the specialised department and the SREAE within the Ministry of Health of any event related to the activities carried out at European level in their field of expertise;
- g) informing other experts in the field about the materials, reports and information obtained following participation in working groups or meetings at European level, in order to ensure institutional representativeness and a coherent technical vision in the field;
- h) requesting/receiving advice from the specialised commissions of the Ministry of Health, as well as from the specialised staff within the SREAE;
- i) are responsible for the position adopted on the requested issue;
- j) are obliged to carry out, where appropriate, the necessary legal steps for reimbursement of the amounts for transport costs from European institutions in whose working groups they have participated;
- k) are obliged to send their official e-mail address to the SREAE and to check their e-mail on a daily basis;
- l) to take the necessary steps to implement the decisions adopted within the technical working groups in which they have participated;
- m) to transmit, at the request of the SREAE, information notes regarding the status of negotiations on the expertise file;
- n) participating in the technical working groups in which European ruling provisions are debated; also participating in the activities of the working group related to transposition of European directives or for setup of the legislative framework for enforcement of European regulations;
- o) The coordinator of the technical working group formed by experts informs the SREAE, every six months, on the status of the documents under debate at European level.

**Art. 6** - In the case of travel to participate in a technical working group or a meeting at European level, the working procedure is the following:

a) the specialised department or the competent institution will nominate, through a report, the participation of persons in the technical working groups, after a prior discussion with the expert proposed for participation, which will be sent to the SREAE, which will start the travel formalities (approval report, travel order);

b) when there is no nomination from the specialised department sent to the SREAE, within 24 hours after receiving the convocation to the technical working group, the SREAE may nominate 1-2 experts with responsibilities in the specialised field provided for in this Order for participation in the technical working groups;

c) The mandate developed by the expert/experts shall be submitted to the specialised department or the superior hierarchical leader, as the case may be, for approval, as follows:

1. if the mandate is approved, the expert/experts submit(s) the mandate, at least 48 hours before the meeting (on paper and in electronic format), to the SREAE for approval, together with the documents on the basis of which it was developed in electronic format;

2. The SREAE sends the mandate for approval to the Ministry of Foreign Affairs;

3. in case of disapproval or a negative opinion, the expert(s) will rewrite the mandate according to observations. The mandate prepared by the expert(s) is sent to the SREAE both on paper and in electronic format;

d) the expert supports Romania's position in the meetings in which they participate, based on the approved mandate;

e) if last-minute amendments show up during debates, resulting in exceeding the limits of action of the elaborated mandate, the expert/representative of the Ministry of Health present at the meeting will act, as appropriate, as follows:

1. if the proposed amendments do not affect the limits of the approved mandate, the expert supports the position in the mandate and abstains on new amendments, and within 48 hours after the end of the meeting, following consultations with responsible institutions, they shall transmit the position on the respective amendments, in written form;

2. if the proposed amendments entirely or partially contradict the content of the mandate or introduce substantial changes, the expert shall abstain, and then develop a new position within the time limit and under the conditions provided for in point 1. This new position will be expressed through a new mandate which follows the same approval procedure;

d) upon returning to the country, the expert shall draft and submit to the specialised department and the SREAE, within maximum two working days, the travel report, both on paper and in electronic format. At the same time, they shall submit the travel report, for information, in electronic format, to the other members of the technical working group in the respective field. In the travel report, the expert shall present the steps taken to clarify and transmit Romania's position for the situations of abstention described in letter e); in case of online participation, the expert shall draft and submit to the specialised department and the SREAE, within maximum two working days, a report, both on paper and in electronic format;

e) the conclusions and proposals of the experts mentioned in the travel report will be analysed by the specialised department and, where appropriate, will be brought to the attention of the Minister of Health, to further be correlated with the policy in the field of the Ministry of Health;

f) after drafting the travel report, the expert will send to the specialised department of the Ministry of Health and the field Coordinator, in electronic format, copies of the

documents attached to the travel report in order to complete the thematic file. At the same time, each expert will draw up, in order to have a coherent record of the field they manage, their own thematic file, which shall be updated whenever necessary;

g) if, for objective reasons, the expert(s) cannot participate in a technical working group or the issue discussed is complex, covering several fields, the SREAE proposes the participation of a representative from the SREAE, who will support the mandate developed by the experts in the field. At the same time, the specialised staff from the SREAE may accompany the experts to the meetings of the technical working groups in order to collaborate and ensure fulfilment of the commitments assumed by them. The representation of the Ministry of Health at high-level meetings (high level group) or at European conferences requiring high-level participation shall be based on the nomination of the Minister of Health or the Coordinating State Secretary of the respective field.

**Art. 7 – The SREAE has the following duties:**

- a) coordinating the technical working group formed by experts, established by this Order, and ensuring compliance with its provisions;
- b) monitoring the process of developing Romania's position in various working groups at European level;
- c) advising the specialised departments of the Ministry of Health in the process of developing mandates, reports for negotiation of certain areas/aspects, according to European requirements;
- d) monitoring the representation of Romania at meetings organised by European institutions and supporting the specialised departments in fulfilling the commitments assumed by the Ministry of Health, as a member state of the European Union;
- e) sending the documents necessary for elaboration of the mandates, if these are not sent directly by the European institutions or by the Romanian representation to the experts of the technical working group, in electronic format or, as the case may be, on paper;
- f) sending the experts the invitation to participate in view of elaboration of the nomination report;
- g) approving the mandates of the experts, following approval by the management of the specialised department within the Ministry of Health;
- h) sending the mandates for approval to the General Directorate of European Affairs of the Ministry of Foreign Affairs;
- i) permanently updating the database on the participation of Ministry of Health experts in European working meetings, in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);
- j) preparing the travel file for high-level meetings (with the participation of the Minister of Health or the delegate);

k) prepares the travel documentation (Order of the Minister of Health, approval report) based on the nomination report of the specialised department/responsible institution;

l) The SREAE may, in certain cases, designate 1-2 experts with responsibilities in the specialised field, as provided for in Art. 5, for participation in technical working groups in the absence of a nomination from the specialised department sent to the SREAE within 24 hours after receiving the convocation to the technical working group or for reasons of incompatibility of the expert.

**Art. 8** - The persons nominated in Art. 2 and the specialised structures within the Ministry of Health, the National Agency for Medicines and Medical Devices of Romania, the National Health Insurance House, the National Institute of Public Health and the other institutions shall carry out the provisions of this Order.

**Art. 9** - Failure to fulfil the duties provided for in Articles 5 and 6 constitutes a breach of official duties and entails the liability of the expert and all responsible persons, in accordance with the legal provisions in force, as well as not being appointed for participation in other working groups.

**Art. 10** - Annexes 1 - 5 are integral parts of this Order.

**Art. 11** – This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,

**Monica-Emanuela Althamer,**

Secretary of state



## **Annex 1**

### **Technical working groups in the healthcare field**

#### **1. Epidemiology and surveillance of communicable diseases:**

1.1. Coordinator: *Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

1.2. Technical group:

a) Anca Sârbu - National Center for Surveillance and Control of Communicable Diseases - The National Institute of Public Health

b) Amalia Șerban - The Ministry of Health

c) Carmen Sima - The Public Health Directorate of Maramureș

d) Camelia Truică - The Public Health Directorate of Călărași

#### **2. Surveillance and control of epidemic and pandemic influenza:**

2.1. Coordinator: Amalia Șerban - The Ministry of Health

2.2. Technical group:

a) *Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

b) Mihaela Lazar - The 'Cantacuzino' National Medico-Military Institute for Research and Development

c) Odette Popovici - The National Institute of Public Health

#### **3. Romania's representation at the European Centre for Disease Prevention and Control - ECDC at:**

3.1. Board of directors:

3.1.1. Amalia Șerban, member - The Ministry of Health

3.1.2. Anca Sârbu, alternate member - National Center for Surveillance and Control of Communicable Diseases - The National Institute of Public Health

3.2. Advisory council:

3.2.1. *Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

3.2.2. Alternate member: Radu Cucuiu - The National Institute of Public Health

#### **4. Coordination Group for Health Promotion, Disease Prevention and Management of Noncommunicable Diseases:**

4.1. Coordinator: *Florentina Furtunescu - The National Institute of Public Health*

4.2. Subgroup - *The Healthier together – EU non-communicable diseases (NCD)*

a) *Florin Buicu - The National Institute of Public Health*

b) *Claudia Dima - The National Institute of Public Health*

c) *Alexandra Cucu - The National Institute of Public Health*

d) *Eugenia Bratu - The National Institute of Public Health*

#### 4.3. Subgrup cancer:

a) *Michael Schenker - The University of Medicine and Pharmacy of Craiova*

b) *Carmen Ungurean - The National Institute of Public Health*

c) *Adriana Melnic - The National Institute of Public Health'*

### 5. Vaccination:

5.1. Coordinator: *Amalia Șerban - The Ministry of Health*

5.2. :

a) *Alexandru Rafila - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

b) *Aurora Stănescu - The National Institute of Public Health*

c) *Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

d) *Gindrovel Dumitra – The National Society of Family Medicine – the Vaccinology Group, The University of Medicine and Pharmacy of Craiova*

### 6. Fighting cancer:

6.1. Coordinator: *Michael Schenker, Associate professor, PharmD - The University of Medicine and Pharmacy of Craiova*

6.2. Technical group:

a) *Gabriel Kacso - The 'Iuliu Hatieganu' University of Medicine and Pharmacy of Cluj-Napoca*

b) *Alina Daniela Tănase – The Faculty of Medicine of the 'Titu Maiorescu' University of Bucharest*

c) *Daniela Zob - The 'Prof. Dr. Al. Trestioreanu' Oncology Institute*

d) *Carmen Ungurean - The National Institute of Public Health*

### 7. Tuberculosis surveillance and control:

7.1. Coordinator: *Mirela Tudorache – The Dispensary for Tuberculosis, Sector 3, Bucharest*

7.2. Technical group:

a) *Ioana Munteanu - The 'Marius Nasta' Institute of Pneumophthisiology*

b) *Gilda Popescu - The 'Marius Nasta' Institute of Pneumophthisiology*

c) *Roxana Mihaela Coriu - The 'Marius Nasta' Institute of Pneumophthisiology*

d) *Irina-Roxana Strâmbu - The 'Marius Nasta' Institute of Pneumophthisiology*

e) *Odette Popovici - The National Institute of Public Health - National Center for Surveillance and Control of Communicable Diseases*

f) *Florentina Furtunescu - The National Institute of Public Health*

### 8. Healthcare-related infections, microbial resistance and antibiotic consumption:

8.1. Coordinator: *Amalia Șerban - The Ministry of Health*

8.2. Technical group:

- a) Alexandru Rafila - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest
- b) Andreea Niculcea - The National Institute of Public Health
- c) Roxana Șerban - The National Institute of Public Health
- d) Gabriel Popescu - The 'Prof. Dr. Matei Bals' National Institute for Infectious Diseases, Bucharest
- e) Maria Nica – The 'Dr. Victor Babeș' Clinical Hospital for Infectious and Tropical Diseases of Bucharest
- f) Dorina Maria Crăciun - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest
- g) Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania

## **9. Health promotion and health education:**

9.1. *Coordinator: Alexandra Cucu - The National Institute of Public Health*

9.2. *Technical group:*

- a) *Carmen Domnariu - The National Institute of Public Health*
- b) *Adela Cojan - The National Institute of Public Health*
- c) *Claudia Dima - The National Institute of Public Health*
- d) *Petru Sandu - The National Institute of Public Health*

## **10. Tobacco control:**

10.1. *Coordinator: Alexandra Cucu - The National Institute of Public Health*

10.2. *Technical group:*

- a) *Simona Pârnu - The National Institute of Public Health*
- b) *Anda Curta - The National Institute of Public Health*
- c) *Cristian Bălan - The National Institute of Public Health*
- d) *Gabriela Cilincă - The National Institute of Public Health*
- e) *Oana Miron - The Ministry of Health.*

## **11. Tobacco ingredients:**

11.1. *Coordinator: Gabriela Cilincă - The National Institute of Public Health*

11.2. *Technical group:*

- a) *Doina Todea - The University of Medicine and Pharmacy, Cluj-Napoca*
- b) *Cristian Bălan - The National Institute of Public Health*
- c) *Adrian Falca - The Ministry of Health*
- d) *Oana Miron - The Ministry of Health'*

## **12. Alcohol intake control:**

12.1. *Coordinator: Claudia Dima - The National Institute of Public Health*

12.2. *Technical group:*

- a) *Gabriela Nicoleta Chițac - The National Institute of Public Health*
- b) *Ciprian Ursu - The National Institute of Public Health*
- c) *Adela Cojan - The National Institute of Public Health*

## **13. Prevention of drug addiction:**

13.1. Coordinator: Teodora Ciolompea – The ‘Sfântul Stelian’ Youth Drug Addiction Assessment and Treatment Center

13.2. Technical group:

- a) Dan Roșca – The ‘Prof. Dr. Al. Obregia’ Clinical Hospital of Psychiatry of Bucharest
- b) Laura Iuliana Bălășan - The National Institute of Public Health

#### **14. Occupational medicine:**

14.1. Coordinator: Marina Ruxandra Oțelea - The ‘Carol Davila’ University of Medicine and Pharmacy, Bucharest

14.2. Technical group:

- a) Horațiu Moldovan - The Ministry of Health
- b) Liliana Râpaș - The Public Health Directorate of Bucharest
- c) Felicia Steliana Popescu - The National Institute of Public Health
- d) Rita Ghitulescu - The National Institute of Public Health
- e) Dana Mateș - The National Institute of Public Health
- f) Otilia Pupazan - The National Institute of Public Health

#### **15. Ionising radiations:**

15.1. Coordinator: Alina Dumitrescu - The National Institute of Public Health

15.2. Technical group:

- a) Olga Girjoaba - The National Institute of Public Health
- b) Loredana Bogdan - The National Institute of Public Health
- c) Irina Anca Popescu - The National Institute of Public Health
- d) Oana Miron - The Ministry of Health
- e) Ion Vasilica - The National Institute of Public Health

#### **16. Nutritional labelling, nutritional and health claims:**

16.1. Coordinator: Nicoleta Florescu - The National Institute of Public Health

16.2. Technical group:

- a) Mirela Nedelescu - The National Institute of Public Health
- b) Marta Petre - The National Institute of Public Health
- c) Daniela Cîrnatu - The National Institute of Public Health
- d) Alina Dragomirișteanu - The Ministry of Health
- e) Preoteasa Antonela - The Ministry of Health

#### **17. Foods for special nutritional purposes:**

17.1. Coordinator: Cristina Viman - The National Institute of Public Health

17.2. Technical group:

- a) Daniela Nuță - The National Institute of Public Health
- b) Cristina Câmpeanu - The National Institute of Public Health
- c) Mirela Nedelescu - The National Institute of Public Health

d) Antonela Preoteasa - The Ministry of Health.

#### **18. Additives, enzymes, flavours:**

18.1. Coordinator: Corina Zugravu - The National Institute of Public Health

18.2. Technical group:

a) Aura Copciag - The Public Health Directorate of Argeş

b) Horaşiu Zapîrţan - The National Institute of Public Health

c) Mirela Nedelescu - The National Institute of Public Health

d) Anamaria Farr - The National Institute of Public Health

#### **19. Genetically modified organisms:**

19.1. Coordinator: Anca Roncea - The National Institute of Public Health

19.2. Technical group:

a) Diana Costin - The National Institute of Public Health

b) Simona Bădoi - The National Agency for Medicines and Medical Devices of Romania

#### **20. Food contact materials:**

20.1. Coordinator: Gabriela Cilincă - The National Institute of Public Health

20.2. Technical group:

a) Oana Copoiu - The National Institute of Public Health

b) Madalina Ghita - The National Institute of Public Health

c) Attila Csiszer - The National Institute of Public Health

d) Antonela Preoteasa - The Ministry of Health

#### **21. Water contact materials:**

\*\*\* Repealed through Order of the Minister of Health no. 4.330/2024 of 30 August 2024

#### **22. Mineral water:**

22.1. Coordinator: Klara Engi - The National Institute of Public Health

22.2. Technical group:

a) Csiszer Attila - The National Institute of Public Health

b) Flavia Edda Prodan - The National Institute of Public Health

c) Carmen Tulbure - The National Institute of Public Health

#### **23. New foods:**

23.1. Coordinator: Daniela Nuţă - The National Institute of Public Health

23.2. Technical group:

a) Nicoleta Florescu - The National Institute of Public Health

b) Horaşiu Zapîrţan - The National Institute of Public Health

c) Cristina Câmpeanu - The National Institute of Public Health

d) Alina Dragomirişteanu - The Ministry of Health

**24. Food supplements and foods to which vitamins, minerals and other substances have been added:**

24.1. *Coordinator: Daniela Cîrnatu - The National Institute of Public Health*

24.2. *Technical group:*

a) *Nicoleta Florescu - The National Institute of Public Health*

b) *Mirela Nedelescu - The National Institute of Public Health*

c) *Cristina Viman - The National Institute of Public Health*

d) *Marta Petre - The National Institute of Public Health*

e) *Antonela Preoteasa - The Ministry of Health*

f) *Andrei Codruț Vrăjitoru - The National Agency for Medicines and Medical Devices of Romania*

**25. Foods and food ingredients treated with ionizing radiation:**

25.1. *Coordinator: Cristina Otilia Câmpeanu - The National Institute of Public Health*

25.2. *Technical group:*

a) *Nicoleta Florescu - The National Institute of Public Health*

**26. Blood transfusion - Blood and blood components:**

26.1. *Coordinator: The Regional Blood Transfusion Center - Constanța*

26.2. *Technical group:*

a) *Georgeta Hanganu - The Blood Transfusion Center of Prahova*

b) *Aurel Marc Andrei Rosin - The Blood Transfusion Center of Covasna*

c) *Raluca Cruceat - The Blood Transfusion Center of Ialomița*

d) *Iulia Bogdan - The Ministry of Health*

e) *George Șuicu - The Ministry of Health*

**27. Tissues, cells, organs and transplantation:**

27.1. *Coordinator: Ioana Adina Rugescu - The National Transplant Agency*

27.2. *Technical group:*

a) *Guenadiy Roumenov Vatachki - The National Transplant Agency*

b) *Andrei Leșan - The National Transplant Agency*

c) *Andrei-Constantin Nica - The National Transplant Agency*

d) *Raluca Neagu-Movilă - The National Transplant Agency*

e) *Traian Laurian Arghisan - The National Registry of Stem Cell Donors*

f) *Ionuț Alexandru Teodoriu - The National Transplant Agency*

g) *Mihaela Necula - The Ministry of Health*

h) *George Șuicu - The Ministry of Health*

i) *Silviu Istrate - The National Agency for Medicines and Medical Devices of Romania*

j) *Laura Petcu - The Ministry of Health*

**28. Water:**

28.1. *Drinking water:*



28.1.1. *Coordinator: Adriana Cârlan - The National Institute of Public Health*

28.1.2. *Technical group:*

- a) *Andra Neamțu - The National Institute of Public Health*
- b) *Cătălin Staicu - The National Institute of Public Health*
- c) *Nicoleta Lemne - The National Institute of Public Health*
- d) *Liliana Neagu - The National Institute of Public Health*
- e) *Ioan Chirilă - The National Institute of Public Health*
- f) *Ileana Văcaru - The Public Health Directorate of Alba*

28.2. *Water contact materials:*

28.2.1. *Coordinator: Irina Stoian - The National Institute of Public Health*

28.2.2. *Technical group:*

- a) *Attila Csiszer - The National Institute of Public Health*
- b) *Nicoleta Lemne - The National Institute of Public Health*
- c) *Alina Bratan - The National Institute of Public Health*
- d) *Călina Creța - The National Institute of Public Health*
- e) *Ioan Chirilă - The National Institute of Public Health*
- f) *Liliana Neagu - The National Institute of Public Health*

28.3. *Bath water*

28.3.1. *Coordinator: Radu Androne - The National Institute of Public Health*

28.3.2. *Technical group:*

- a) *Luiza Caruceru - The Public Health Directorate of Constanța*
- b) *Liliana Neagu - The National Institute of Public Health*
- c) *Rodica Alina Ochea - The Public Health Directorate of Constanța*
- d) *Giorgiana Maria Badea - The Public Health Directorate of Tulcea*

## **29. Medical waste:**

29.1. *Coordinator: Oana Cureau - The National Institute of Public Health*

29.2. *Technical group:*

- a) *Ana Maria Bratu - The National Institute of Public Health*
- b) *Viorel Gliga - The National Institute of Public Health*
- c) *Brândușa Bocoș - The National Institute of Public Health*
- d) *Cristiana Cîrlan - The Ministry of Health*
- e) *Alina Dragomirișteanu - The Ministry of Health*

## **30. Biocide:**

30.1. *Coordinator: Simona Drăgoiu - The National Institute of Public Health*

30.2. *Technical group:*

- a) *Horațiu Marcu - The Ministry of Health*
- b) *Cristiana Cîrlan - The Ministry of Health*
- c) *Madalina Ghiță - The National Institute of Public Health*
- d) *Mihaela Pribu - The National Institute of Public Health*
- e) *Iuliana Radu - The National Institute of Public Health*
- f) *Victor Lungu - The National Institute of Public Health*

### **31. Cosmetics:**

31.1. Coordinator: *Simona Pârvu - The National Institute of Public Health*

31.2. Technical group:

- a) *Irina Tănase - The National Institute of Public Health*
- b) *Mihaela Coman - The National Institute of Public Health*
- c) *Andrei Farcaș - The National Institute of Public Health*
- d) *Ramona Fătu - The Public Health Directorate of Buzău*
- e) *Falca Adrian - The Ministry of Health*
- f) *Raluca Mușat - The Ministry of Health.*

### **32. Mental health and degenerative diseases:**

32.1. Mental health:

32.1.1. Coordinator: *Teodora Ciolompea - The 'Sfântul Stelian' Youth Drug Addiction Assessment and Treatment Center*

32.1.2. Technical group:

- a) *Irina Minescu - The 'Voila' Psychiatric Hospital*
- b) *Gabriel Diaconu - The Ministry of Health*
- c) *Cristina Gianina Anghel - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
- d) *Mihaela Luminița Staicu - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

32.2. Alzheimer's:

32.2.1. Technical group:

- a) *Cătălina Tudose - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
- b) *Bogdan Popescu - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*

32.3. Elderly population:

32.3.1. Coordinator: *Dana Galieta Minca - The National Institute of Public Health*

32.3.2. Technical group:

- a) *Gabriel Ioan Prada – The 'Ana Aslan' National Institute of Gerontology and Geriatrics*

### **33. Injury and accident prevention:**

33.1. Coordinator: *Petru Sandu - The National Institute of Public Health*

33.2. Technical group:

- a) *Cristian Boeriu – The Mobile Emergency Service for Resuscitation and Extrication of Târgu Mureș*
- b) *Horățiu Mîndăianu - The Prahova Ambulance Service*



**34. The European Union's action programme in the field of health for 2021 - 2027 (EU4Health):**

34.1. *Coordinator: Cristian Vlădescu - The National Institute for Health Services Management*

34.2. *Technical group:*

- a) *Silvia Gabriela Scîntee - The National Institute for Health Services Management*
- b) *Florentina Furtunescu - The National Institute of Public Health*
- c) *Florin Buicu - The National Institute of Public Health*
- d) *Diana Virtaci - The Ministry of Health*
- e) *Monica Diana Isăilă - The Ministry of Health*
- f) *Laura Petcu - The Ministry of Health*
- g) *Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania*
- h) *Monica Negovan - The Ministry of Health*

**35. Diabetes mellitus, endocrine diseases:**

35.1. *Diabetes mellitus:*

35.1.1. *Coordinator: Anca Mihaela Pantea Stoian – The ‘Prof. Dr. N. Paulescu’ National Institute for Diabetes, Nutrition and Metabolic Diseases of Bucharest*

35.1.2. *Technical group:*

- a) *Roxana Stoica - The ‘Carol Davila’ University of Medicine and Pharmacy, Bucharest*
- b) *Cornelia Bala - The ‘Iuliu Hatieganu’ University of Medicine and Pharmacy of Cluj-Napoca*
- c) *Carmen Angheluță - The National Institute of Public Health*

35.2. *Boli endocrine:*

35.2.1. *Coordinator: Cătălina Poiană - The ‘C.I. Parhon’ National Institute of Endocrinology*

35.2.2. *Technical group:*

- a) *Ghervan Cristina - The ‘Iuliu Hatieganu’ University of Medicine and Pharmacy of Cluj-Napoca*
- b) *Iuliana Gherlan - The ‘C.I. Parhon’ National Institute of Endocrinology of Bucharest*

**36. Health services and medical care (cross-border healthcare):**

36.1. *Coordinator: Andreea Găraiacu - The National Health Insurance House*

36.2. *Technical group:*

- a) *Roxana Hainagiu - The Ministry of Health*
- b) *Costin Iliuță - The Ministry of Health*

**37. Patient safety and information for patients:**

37.1. *Coordinator: Roxana Șerban - The National Institute of Public Health*

37.2. *Technical group:*

- a) *Costin Iliuță - The Ministry of Health*
- b) *Cristian Calomfirescu - The National Institute of Public Health*
- c) *Roxana Dondera - The National Agency for Medicines and Medical Devices of Romania*
- d) *Monica Negovan - The Ministry of Health*
- e) *Carmen Vișănoiu - The Ministry of Health*

**38. Toy safety and youth issues:**

38.1. *Coordinator: Adriana Samoila - The National Institute of Public Health*

38.2. *Technical group:*

- a) *Alexandra Viman - The National Institute of Public Health*
- b) *Alina Hodarnau - The National Institute of Public Health*
- c) *Elena-Geanina Moldovan - The National Institute of Public Health*
- d) *Constantina Albu - The National Institute of Public Health*

**39. Road safety (drivers' health issues - ophthalmology, mental illness, diabetes mellitus):**

39.1. *Coordinator: Ruxandra Dănciulescu - The 'C.I. Parhon' National Institute of Endocrinology Of Bucharest (Diabet zaharat)*

39.2. *Technical group:*

- a) *Aurel Nirestean - The University of Medicine and Pharmacy of Târgu Mureș (Mental illnesses)*
- b) *Ciprian Băcilă – The Faculty of Medicine - The 'Lucian Blaga' University of Sibiu*

**40. Reproductive health:**

40.1. *Coordinator: Mihai Horga - The East European Institute for Reproductive Health*

40.2. *Technical group:*

- a) *Alin Nicolae Stănescu – The 'Alessandrescu-Rusescu' National Institute for Child and Maternal Health*
- b) *Szabo Bela - The Târgu Mureș Emergency Clinical County Hospital*
- c) *Simona Duță – The 'Filantropia' Clinical Hospital*
- d) *Mihaela Buiciuc - The Ministry of Health.*

**41. Health information systems:**

41.1. *Coordinator: Alexandru Rogobete - The Ministry of Health*

41.2. *Technical group:*

- a) *Florentina Furtunescu - The National Institute of Public Health*
- b) *Cristian Calomfirescu - The National Institute of Public Health*
- c) *Marius Ciutan - The National Institute for Health Services Management*

**42. eHealth:**

42.1. *Coordinator: Alexandru Florin Rogobete - The Ministry of Health*

42.2. *Technical group:*

- a) *Laura Petcu - The Ministry of Health*
- b) *Claudia Alexandra Costin - The National Health Insurance House*
- c) *Monica Negovan - The Ministry of Health,*
- d) *Andreea Garaiacu - The National Health Insurance House*
- e) *Oana Lazăr - The National Health Insurance House*
- f) *Nicoleta Bogăceanu - The Ministry of Health*
- g) *Cristian Calomfirescu - The National Institute of Public Health*
- h) *Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania*
- i) *Sorin Timofei - The National Agency for Medicines and Medical Devices of Romania*
- j) *Claudia Dima - The National Institute of Public Health*
- k) *Bogdan Predescu - The Ministry of Health*
- l) *Adrian-Stelian Dumitru - The Ministry of Health*
- m) *Edwin Harabagiu - The Ministry of Health*
- n) *Andrei Bucșan - The Ministry of Health*

#### **43. The Health Security Committee:**

- 43.1. Coordinator: *Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
- 43.2. Technical group:
  - a) *Amalia Șerban - The Ministry of Health*
  - b) *Alexandru Rafila - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
  - c) *Lavinia Rusu - The National Institute of Public Health*
  - d) *Radu Cucuiu - The National Institute of Public Health.*

#### **44. Disabilities and rehabilitation:**

- 44.1. Coordinator: *Mihai Berteanu – the Elias University Emergency Hospital - Bucharest*
- 44.2. Technical group:
  - a) *Delia Cintează - The National Institute for Rehabilitation, Physical Medicine and Balneoclimatology, Bucharest*
  - b) *Adrian Bighea - The University of Medicine and Pharmacy of Craiova*
  - c) *Daiana Popa – The 'Băile Felix' Medical Rehabilitation Clinical Hospital - Bihor*
  - d) *Paraschiva Postolache – The University of Medicine and Pharmacy - Iași*

#### **45. Oral and Maxillofacial Surgery:**

- 45.1. *Cristian Dinu - The 'Iuliu Hatieganu' University of Medicine and Pharmacy of Cluj-Napoca*

#### **46. Plant protection products:**

- 46.1. Coordinator: *Mihaela Pribu - The National Institute of Public Health*
- 46.2. Technical group:
  - a) *Irina Alexandrescu - The National Institute of Public Health*
  - b) *Gabriela Brânzei - The National Institute of Public Health*

- c) *Camelia Florina Raicea - The National Institute of Public Health*
- d) *Irina Tănase - The National Institute of Public Health*
- e) *Daniela Păușan - The National Institute of Public Health*

**47. Classification, labelling and packaging of REACH and CLP substances:**

- 47.1. *Coordinator: Mihaela Pribu - The National Institute of Public Health*
- 47.2. *Technical group:*
  - a) *Oana Copoiu - The National Institute of Public Health*
  - b) *Viorel Cazuc - The National Institute of Public Health*
  - c) *Edda Prodan - The National Institute of Public Health*
  - d) *Irina Alexandrescu - The National Institute of Public Health*

**48. Health in relation to the environment and climate change:**

- 48.1. *Coordinator: Ioan Chirilă - The National Institute of Public Health*
- 48.2. *Technical group:*
  - a) *Oana Iacob - The National Institute of Public Health*
  - b) *Andra Neamțu - The National Institute of Public Health*
  - c) *Irina Tănase - The National Institute of Public Health*
  - d) *Angelica Marilena Voinoiu - The National Institute of Public Health*
  - e) *Silvia Elena Teodorescu - The National Institute of Public Health*
  - f) *Alina Dragomirișteanu - The Ministry of Health*

**49. Non-ionizing radiation (electromagnetic fields):**

- 49.1. *Coordinator: Violeta Claudia Calotă - The National Institute of Public Health*
- 49.2. *Technical group:*
  - a) *Cristian Goiceanu - The National Institute of Public Health*
  - b) *Cezar Tazlaoanu - The National Institute of Public Health*
  - c) *Loredana Bogdan - The National Institute of Public Health*
  - d) *Laura Petcu - The Ministry of Health*

**50. Connection with the European Chemicals Agency (ECHA)**

- 50.1. *Coordinator: Alexandru Miclea - The National Institute of Public Health*
- 50.2. *Technical group:*
  - a) *Ana Maria Oancea - The National Institute of Public Health*
  - b) *Emilia Niciu - The National Institute of Public Health*
  - c) *Adriana Andrei - The National Institute of Public Health*
  - d) *Codruța Loigner - The National Institute of Public Health*

**51. Romania's representation in the High-Level Group on Nutrition and Physical Activity:**

- 51.1. *Coordinator: Petru Sandu - The National Institute of Public Health*
- 51.2. *Technical group:*
  - a) *Corina Zugravu - The National Institute of Public Health*

- b) Ciprian Ursu - The National Institute of Public Health
- c) Claudia Dima - The National Institute of Public Health

## **52. The European Network for the Promotion of Health-Enhancing Physical Activity (HEPA)**

- 52.1. Coordinator: Ciprian Ursu - The National Institute of Public Health
- 52.2. Technical group:
  - a) Alexandra Cucu - The National Institute of Public Health
  - b) Petru Sandu - The National Institute of Public Health
  - c) Claudia Dima - The National Institute of Public Health

**53.** Representation of Romania in the Committee on serious cross-border threats to health, in line with Article 18 paragraph 1 of Decision No. 1.082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC):

- 53.1. *Coordinator: Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
- 53.2. *Technical group:*
  - a) *Amalia Șerban - The Ministry of Health*
  - b) *Radu Cucuiu - The National Institute of Public Health*
  - c) *Lavinia Rusu - The National Institute of Public Health*

## **54. Boli rare:**

- 54.1. *Coordinator: Maria Puiu - The 'Louis Turcanu' Emergency Clinical Hospital for Children, Timisoara*
- 54.2. *Technical group:*
  - a) *Adela Chiriță Emandi - The 'Victor Babeș' University of Medicine and Pharmacy, Timișoara*
  - b) *Nicoleta Berbec - The 'Colțea' Clinical Hospital of Bucharest*
  - c) *Emilia Severin - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest*
  - d) *Eusebiu Vlad Gorduza - The 'Gr. T. Popa' University of Medicine and Pharmacy of Iași*
  - e) *Cristina Rusu - The 'Gr. T. Popa' University of Medicine and Pharmacy of Iași*
  - f) *Lidia Onofrei - The Ministry of Health*
  - g) *Iulia Crețu - The Ministry of Health*
  - h) *Denisa Marilena Margină - The National Agency for Medicines and Medical Devices of Romania*

## **55. Indicator systems for evaluating the performance of health systems:**

- 55.1. *Coordinator: Dragoș Garofil – The 'Dr. Carol Davila' Clinical Hospital of Nephrology*
- 55.2. *Technical group:*
  - a) *Eugenia Bratu - The National Institute of Public Health*

- b) *Petru Sandu - The National Institute of Public Health*
- c) *Cristian Calomfirescu - The National Institute of Public Health*
- d) *Claudia Dima - The National Institute of Public Health*
- e) *Aurora Dragomirișteanu - The National Institute for Health Services Management*

#### **56. Romania's representation in the High-Level Group on Public Health:**

56.1. Coordinator: Florentina Furtunescu - The National Institute of Public Health

56.2. Technical group:

- a) Amalia Șerban - The Ministry of Health
- b) Alexandra Cucu - The National Institute of Public Health

#### **57. European reference networks:**

57.1. Coordinator: Maria Puiu - The 'Louis Turcanu' Emergency Clinical Hospital for Children, Timisoara

57.2. Technical group:

- a) Costin Iliuță - The Ministry of Health
- b) Nicoleta Berbec - The Colțea Clinical Hospital of Bucharest
- c) Emilia Severin - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest.

#### **58. Clinical toxicology, toxicological information and medical response in toxicological emergencies:**

58.1. Coordinator: Radu Țincu – The Floreasca Emergency Clinical Hospital of Bucharest

58.2. Technical group:

- a) Gabriela Viorela Nițescu – The 'Grigore Alexandrescu' Children's Emergency Clinical Hospital, Bucharest
- b) Dan Manu – The Forensic Medicine Service of Argeș
- c) Mihaela Purcărea - The National Institute of Public Health
- d) Andrei Farcas - The National Institute of Public Health
- e) Horațiu Marcu - The National Institute of Public Health
- f) Andrei Bucșan - The Ministry of Health
- g) Neluța Popescu - The Ministry of Health

#### **59. HIV/AIDS prevention and control:**

59.1. Coordinator: Mariana Mărdărescu - The 'Prof. Dr. Matei Bals' National Institute for Infectious Diseases, Bucharest

59.2. Technical group:

- a) Irina Magdalena Dumitru - The Infectious Diseases Hospital of Constanța
- b) Adrian Marinescu - The 'Prof. Dr. Matei Bals' National Institute for Infectious Diseases, Bucharest



## **60. Genetics:**

60.1. Coordinator: Maria Puiu - The 'Louis Turcanu' Emergency Clinical Hospital for Children, Timisoara

60.2. Technical group:

- a) Conf. dr. Ioana Streață - The University of Medicine and Pharmacy of Craiova
- b) Claudia Bănescu - The 'George Emil Palade' University of Medicine and Pharmacy of Târgu Mureș.

## **61. The High-Level Group on the European Health Emergency preparedness and Response Authority**

61.1. Coordinator: Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest

61.2. Technical group:

- a) Amalia Șerban - The Ministry of Health
- b) Monica Negovan - The Ministry of Health
- c) Radu Cucuiu - The National Institute of Public Health
- d) Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania

61.3. The Subtechnical group for joint purchases:

61.3.1. Coordinator: Amalia Șerban - The Ministry of Health

61.3.2. Technical group:

- a) Grațiela Bobe - The Ministry of Health
- b) Costin Iliuță - The Ministry of Health
- c) Claudia Boloagă - The Ministry of Health
- d) Cristian Safta - The Ministry of Health
- e) Liliana Buteșteanu - The Ministry of Health
- f) Daniela Chiru - The Ministry of Health

## **62. Important Project of Common European Interest in Health - IPCEI:**

62.1. Coordinator: Costin Iliuță - The Ministry of Health

62.2. Technical group:

- a) Monica Negovan - The Ministry of Health
- b) Adrian-Stelian Dumitru - The Ministry of Health
- c) Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania
- d) Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania
- e) Cristina Gavrilă - The National Agency for Medicines and Medical Devices of Romania

## **63. The Group for the International Agreement on Pandemic Preparedness and Action and for International Health Regulations:**

63.1. Coordinator: Radu Cucuiu - The National Institute of Public Health

63.2. Technical group:

- a) *Lavinia Rusu - The National Institute of Public Health*
- b) *Amalia Șerban - The Ministry of Health*

**64. Technical group on COVID-19 Related issues**

64.1. *Coordinator: Adriana Pistol - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest:*

64.2. *Technical group:*

- a) *Amalia Șerban - The Ministry of Health*
- b) *Lavinia Rusu - The National Institute of Public Health*
- c) *Radu Cucuiu - The National Institute of Public Health*
- d) *Cristian Calomfirescu - The National Institute of Public Health*

**65. The European Union Vaccines Committee:**

65.1. *Coordinator: Amalia Șerban - The Ministry of Health*

65.2. *Technical group:*

- a) *Monica Lazar - The Ministry of Health*
- b) *Iulia Bogdan - The Ministry of Health*
- c) *Aurora Stănescu - The National Institute of Public Health*
- d) *Simona Ruță - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest.*



## Annex 2

### Technical working groups in the pharmaceutical and medical device fields

#### 1. Medicinal products for human use:

1.1. Coordinator: Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania

1.2. Technical group:

a) Elena Valeria Brodeală - The National Agency for Medicines and Medical Devices of Romania

b) Roxana Dondera - The National Agency for Medicines and Medical Devices of Romania

c) Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania

d) Andrei Codruț Vrăjitoru - The National Agency for Medicines and Medical Devices of Romania

e) Mirela Tavakol - The National Agency for Medicines and Medical Devices of Romania

f) Simona Bădoi - The National Agency for Medicines and Medical Devices of Romania

g) Cristina Gavrila - The National Agency for Medicines and Medical Devices of Romania

h) Carmen Purdel - The National Agency for Medicines and Medical Devices of Romania

i) Monica Negovan - The Ministry of Health

j) Adrian-Stelian Dumitru - The Ministry of Health

k) Dana Marin - The National Agency for Medicines and Medical Devices of Romania

l) Olimpia Neagu - The National Agency for Medicines and Medical Devices of Romania

m) Daniela Chiru - The Ministry of Health

n) Roxana Ștefania Udrescu - The National Agency for Medicines and Medical Devices of Romania

o) Ioana Ivănoiu - The National Agency for Medicines and Medical Devices of Romania

p) Alexandru Ciolan - The Ministry of Health

## **2. Biological products for human use:**

2.1. Coordinator: *Mirela Tavakol - The National Agency for Medicines and Medical Devices of Romania*

2.2. Technical group:

- a) *Gianina Andrei - The National Agency for Medicines and Medical Devices of Romania*
- b) *Daniela Mădălina Doru - The National Agency for Medicines and Medical Devices of Romania*

## **3. Pharmacovigilance:**

3.1. Coordinator: *Roxana Ștefania Udrescu - The National Agency for Medicines and Medical Devices of Romania*

3.2. Technical group:

- a) *Irina Sandu - The National Agency for Medicines and Medical Devices of Romania*
- b) *Denisa Janță - The National Institute of Public Health*
- c) *Carmen Vișănoiu - The Ministry of Health*

## **4. Falsified medicinal products:**

4.1. Coordinator: *Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania*

4.2. Technical group:

- a) *Simona Manole - The National Agency for Medicines and Medical Devices of Romania*
- b) *Cristina Gavrilă - The National Agency for Medicines and Medical Devices of Romania*
- c) *Andrei Grigore - The National Agency for Medicines and Medical Devices of Romania*
- d) *Adrian-Stelian Dumitru - The Ministry of Health*

## **5. Clinical trials:**

5.1. Coordinator: *Mirela Viță - The National Agency for Medicines and Medical Devices of Romania*

5.2. Technical group:

- a) *Adina Iuliana Pîrvu - The National Agency for Medicines and Medical Devices of Romania*
- b) *Silviu Istrate - The National Agency for Medicines and Medical Devices of Romania*

## **6. Ethics in clinical research:**

6.1. Technical group: *Monica Diana Isăilă - The Ministry of Health*

## **7. Medicinal product policy, medicinal product pricing, medicinal product reimbursement and relative effectiveness:**

7.1. Coordinator: *Monica Negovan - The Ministry of Health*

7.2. Technical group:

- a) *Adrian-Stelian Dumitru - The Ministry of Health*
- b) *Monica Daniela Lazăr - The Ministry of Health*
- c) *Bogdan Predescu - The Ministry of Health*
- d) *Daniela Chiru - The Ministry of Health*
- e) *Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania*
- f) *Octavian Matei - The National Agency for Medicines and Medical Devices of Romania*
- g) *Mihaela Lavinia Popescu - The National Agency for Medicines and Medical Devices of Romania*
- h) *Alexandru Ciolan - The Ministry of Health*

## **8. Medical devices:**

8.1. *Coordinator: Alexandru George Florea - The National Agency for Medicines and Medical Devices of Romania*

8.2. *Technical group:*

*\Elena Valeria Brodeală - The National Agency for Medicines and Medical Devices of Romania*

- a) *Valentin Dincă - The National Agency for Medicines and Medical Devices of Romania*
- b) *Oana Laura Arsenescu - The National Agency for Medicines and Medical Devices of Romania*
- c) *Anda Luana Fuior - The National Agency for Medicines and Medical Devices of Romania*
- d) *Elena Ursuleț - The National Agency for Medicines and Medical Devices of Romania*
- e) *Cristina Gabriela Vulcăneanu - The National Agency for Medicines and Medical Devices of Romania*
- f) *Otilia Roșioru - The National Agency for Medicines and Medical Devices of Romania*
- g) *Sorina Loghin - The National Agency for Medicines and Medical Devices of Romania*
- h) *George-Marian Ghițulescu - The National Agency for Medicines and Medical Devices of Romania*
- i) *Mihaela Voicu - The National Agency for Medicines and Medical Devices of Romania*
- j) *Laura Andreea Goșu - The National Agency for Medicines and Medical Devices of Romania*
- k) *Mihaela Crețu - The National Agency for Medicines and Medical Devices of Romania*
- l) *Cristina Gavrilă - The National Agency for Medicines and Medical Devices of Romania.*

m) *Rodica Gabriela Pietriș - The National Agency for Medicines and Medical Devices of Romania*

n) *Cătălin Vlăsceanu - The National Agency for Medicines and Medical Devices of Romania*

o) *Tatiana Elisabeta Miercure - The Ministry of Health*

p) *Adrian-Stelian Dumitru - The Ministry of Health*

## **9. Health technologies assessment**

9.1. *Coordinator: Răzvan Mihai Prisada - The National Agency for Medicines and Medical Devices of Romania*

9.2. *Technical group:*

a) *Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania*

b) *Alina Loredana Mălăescu - The National Agency for Medicines and Medical Devices of Romania*

c) *Mihaela Lavinia Popescu - The National Agency for Medicines and Medical Devices of Romania*

d) *Cristina Ligia Tuțu - The National Agency for Medicines and Medical Devices of Romania*

e) *Octavian Matei - The National Agency for Medicines and Medical Devices of Romania*

f) *Otilia Roșioru - The National Agency for Medicines and Medical Devices of Romania*

g) *Sorina Loghin - The National Agency for Medicines and Medical Devices of Romania.*

h) *Daniela Chiru - The Ministry of Health*

i) *Monica Negovan - The Ministry of Health*

j) *Edwin Harabagiu - The Ministry of Health*

k) *Călin Jurcă - The Ministry of Health*

## **10. Patient access to innovative therapies:**

10.1. *Coordinator: Felicia Ciulu-Costinescu - The National Agency for Medicines and Medical Devices of Romania*

10.2. *Technical group:*

a) *Costin Iliuță - The Ministry of Health*

b) *Monica Negovan - The Ministry of Health*

c) *Simona Bădoi - The National Agency for Medicines and Medical Devices of Romania*

d) *Mirela Tavakol - The National Agency for Medicines and Medical Devices of Romania*

e) *Mirela Viță - The National Agency for Medicines and Medical Devices of Romania*

*f) Denisa Marilena Margină - The National Agency for Medicines and Medical Devices of Romania*

*g) Alexandru Ciolan - The Ministry of Health*

## **Annex 3**

### **Technical working groups in other areas**

#### **1. Bioethics:**

1.1. Coordinator: Klara Brînzaniuc - The University of Medicine and Pharmacy of Târgu Mureş

1.2. Technical group: Beatrice Ioan - The 'Gr. T. Popa' University of Medicine and Pharmacy of Iaşi

#### **2. Recognition of professional qualifications:**

2.1. Coordinator: Aurora Prunescu - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest

2.2. Technical group:

a) Marilena Chivu - The Ministry of Health

b) Iuliana Ganea - The Ministry of Health

c) Gabriela Ionescu - The Ministry of Health

d) Razvan-Daniel Stroe - The Ministry of Health

e) Ioana Mihalea - The Ministry of Health

#### **3. Health communication:**

3.1. Coordinator: Emanuela Schweninger - The Ministry of Health

3.2. Technical group:

a) Oana Grigore - The Ministry of Health

b) Ramona Badea - The Ministry of Health

c) Veronica Zoicaş - The National Institute of Public Health

#### **4. European Union's Health Portal:**

4.1. Coordinator: Irina Gresaru - The Ministry of Health

4.2. Technical group:

a) Mihaela Gîză - The Ministry of Health

b) Cristian Dudu - The Ministry of Health

#### **5. Healthcare human resources:**

5.1. Coordinator: Răzvan-Daniel Stroe - The Ministry of Health

5.2. Technical group:

a) Alexandru Rafila - The 'Carol Davila' University of Medicine and Pharmacy, Bucharest

b) Dragoş Garofil - The 'Dr. Carol Davila' Clinical Hospital of Nephrology

- c) *Teodor Blidaru - The Craiova Emergency Clinical Hospital*
- d) *Bogdan Vinersar - The National Institute of Public Health*
- e) *Marilena Chivu - The Ministry of Health*

## **Annex 4**

Approved,

Name of the specialised department

**General Manager/Manager of the specialised department**

### **TRAVEL REPORT**

Participant (or structure of the delegation, if several people participate in the same meeting):

Working group/field:

Date/Period:

Location:

1. Justification of the action:

- (Summary presentation of the main key points related to the documents under discussion according to the working agenda, concretely and coherently, also specifying the status of the discussions or negotiations that took place and the possibility of resuming the discussions in the meetings of next working groups);

- (Conclusions of the meeting - the hierarchical superior is also announced verbally, as well as other departments involved, in the case of subjects of particular importance) 2. Romania's position and the position of the other member states:

- [The position of Romania (without supporting notes) regarding the topics under discussion, as well as the positions of the other member states, positions which are of major importance in making future decisions, are mentioned in a brief and concise manner.];

- (At the same time, the objectives to be achieved for both Romania and other member states are mentioned, in case possible opposition from some member states is specified during debates, as well as the proposal of possible 'deals' with representatives of other member states during future debates.)

3. Romania's position taken during the meeting in case last-minute amendments (new documents) appeared and if the contact person(s) in the country (who are directly involved in the development of Romania's technical position - including the motivation for this action) was/were contacted:



4. Conclusions/Proposals (a very important section which determines subsequent initiatives of the specialised department/institution in order to develop necessary national ruling provisions):

(Presentation notes:

- the report must be written clearly and concisely, with diacritics, without grammatical errors;
- the report represents a detailed description of all debates which makes anyone who reads it understand the discussions as if they had participated in the respective meeting;
- the report is signed and dated by the participant/participants, who is/are responsible for the statements made, and is handed over to the specialised department (together with the meeting agenda) in order to be included in the thematic file, as well as to the Coordinating State Secretary in order to make any additional resolutions;
- the travel report is sent on paper and in electronic format to the Foreign Relations and European Affairs Service within maximum two days after returning to the country and only in electronic format to the other experts in the field.)

Data

.....

.....

(name and position of the expert)

Signature (on the report sent on  
paper)

Drawn up by

## Annex 5

### MANDATE

- template -

#### a) Romania's negotiating mandate

(meeting type description, level of participation, structured activity, previous meeting, etc.)
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##### **I. Description of representation type**

**II. Brief description of the topic on the agenda of the Council of the European Union or of the committees set up according to the provisions of Regulation (EU) 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 (in line with Government Decision no. 34/2017 on the organisation and operation of the National System for Management of European Affairs in regard to the participation of Romania in the decision-making process within European Union institutions)**

(description of the document and contextual elements related to the issue by highlighting important elements)
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**III. Relevance for Romania: The economic, social and environmental impact on Romania in the case of draft legal acts of the European Union, as well as in the case of proposals for implementing acts of binding legal acts of the European Union (in line with Government Decision no. 34/2017)**

(the relevance of the meeting and the issue for Romania from a social, economic and environmental impact viewpoint, taking into account the possible/potential risks identified)
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**IV. Romania's objectives in relation to the topic on the agenda of the Council of the European Union or of the committees established according to the provisions of Regulation (EU) 182/2011 (in line with Government Decision no. 34/2017)**

(guidance to the receiver regarding Romania's general approach in the negotiations)

(formulation of proposals for Romania's positioning in relation to the topic of the meeting)

**V. Positioning proposals**

**VI. Limits which can be accepted by Romania in the negotiation process (in line with Government Decision no. 34/2017)**

(presentation of Romania's **maximum objectives** with a description of specific elements and Romania's **red lines** with a detailing of specific unacceptable elements)

(The calendar of meetings at COM level and in the Council formations which address the topic is highlighted, placing the emphasis on Romania's participation.)

**VII. Topic follow-up (calendar, attendance)**

**VIII. Contextual elements**

a) Possible negotiating positions of other EU Member States, the European Commission and the European Parliament or its committees (in line with Government Decision no. 34/2017)

(The positions of the other member states shall be identified and the existence/non-existence of a majority on the viewpoints formulated by Romania shall be ascertained.)

b) **Brief presentation of the legal provisions of the European Union in force at European level and other international commitments previously assumed by the Romanian side in the respective field (in line with Government Decision no. 34/2017)**

(Identification of legal provisions in European Union legislation which regulate the issue.)

**c) List of ruling provisions of the Romanian legislation regulating the issue referred to by the draft European Union provision, as well as an analysis of the changes that the adoption of the respective draft European Union provision would entail (in line with Government Decision no. 34/2017)**

(Ruling provisions from the national legislation which deal with the same subject shall be identified; if none, the existence of a regulatory vacuum from a national perspective in this regard shall be noted)

Drawn up by:

**Expert,**

.....

**b) Mandate of representation**

- description of the object, content, purpose and duration of the trip

**I. Description of the trip**

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**II. Description of the representation type**

- description of the foreign partner and the invitation sent to the Romanian party

- description of how travel expenses shall be covered  
(transportation/accommodation/meals)/mention of the means of transport used

### **III. Fees**

- presentation of the delegation's structure (name, position)

### **IV. Structure of the delegation**

### **V. Mandate for discussions**

**V.1. Brief description of the topic(s) on the agenda**

**V.2. Relevance for Romania**

**V.3. Romania's objectives in relation to the topic on the agenda**

**V.4. Positioning proposals**

**V.5. Potential risks**

Drawn up by:

**Expert,**

.....