ORDER No. 522 of 4 April 2019

for amendment of Order of the Minister of Health no. 1.173/2010 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities

Published in: Official Journal of Romania No. 276 of 11 April 2019

On seeing Approval Report no. S8 4.536/4.04.2019 of the Ministry of Health Directorate for Press Relations, European Affairs and International Relations,

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

the Minister of Health hereby issues the following Order:

Article 1 – Order of the Minister of Health no. 1.173/2010 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities, as amended, published in: Official Journal of Romania, Part I, No. 649 of 20 September 2019, is hereby amended as follows:

1. Article 5 (28), a) is hereby amended as follows:

"28. a) Drinking water:

Co-ordinator: Ileana Văcaru, MD - Alba County Public Health Directorate

Alternate: Edit Vartic, MD - National Public Health Institute Technical Group:

- Ioana-Rodica Lupșa, MD National Public Health Institute
- chem. Gabriela Brînzei National Public Health Institute
- chem. eng. Nicoleta Lemne National Public Health Institute
- chem. Dana Rusea National Public Health Institute
- biol. Liliana Neagu National Public Health Institute
- Ileana Anca Badea, MD Arges County Public Health Directorate
- Ioan Chirilă, MD National Public Health Institute".

2. Article 5 (35), a) - e) are hereby amended as follows:

"a) Medicinal products for human use:

Co-ordinator: Marius Daniel Şişu – president of the National Agency for Medicines and Medical Devices (NAMMD)

Technical Group:

- Simona Bădoi, MD NAMMD
- Cristiana Octaviana Ilie, MD NAMMD
- Roxana Stefania Stroe, MD NAMMD
- pharm. Victorita Ivașcu NAMMD
- biol. Mirela Tavakol NAMMD
- pharm. Anca Crupariu NAMMD
- pharm. Monica Daniela Lazăr Ministry of Health
- b) Biological products for human use:

Co-ordinator: biol. Mirela Tavakol - NAMMD

Technical Group:

- biol. Gianina Andrei NAMMD
- Roxana Ştefania Stroe, MD NAMMD
- c) Pharmacovigilance:

Co-ordinator: Roxana Ștefania Stroe, MD - NAMMD

Technical Group:

- pharm. Roxana Dondera NAMMD
- Camelia Lazăr, MD NAMMD
- d) Falsified medicines:

Co-ordinator: Marius Daniel Şişu - NAMMD president

Technical Group:

- Cristina Gavrilă, Legal Advisor NAMMD
- Adina Pîrvu, MD NAMMD
- e) Clinical trials:

Co-ordinator: Marius Daniel Şişu - NAMMD president

Technical Group:

- Mirela Vîţă, MD NAMMD
- Adina Pîrvu, MD NAMMD
- Cristina Gavrilă, Legal Advisor NAMMD".

3. Article 5, 36 - 38 are hereby amended as follows:

"36. Medical devices:

Co-ordinators:

- Marius Daniel Şişu NAMMD president
- eng. Ioana Tene NAMMD

Technical Group:

- eng. Oana Arsenescu NAMMD
- eng. Cristina Durle NAMMD
- eng. Rodica Marinela Chifor NAMMD
- subeng. Margareta Mihalache NAMMD
- eng. Mihaela Buzatu NAMMD
- eng. Mihaela Grigore NAMMD
- eng. Georgeta Herta NAMMD
- eng. Cristina Vulcăneanu NAMMD

- eng. Adrian Pacioaga - NAMMD

37. Assessment of health technologies:

Co-ordinator: Dan Octavian Alexandrescu, MD - Secretary of state, Ministry of Health

Technical Group:

- Roxana Ștefania Stroe, MD NAMMD
- pharm. Felcia Ciulu Costinescu NAMMD
- Cristina Gavrilă, Legal Advisor NAMMD
- 38. Patient access to innovative therapies:

Co-ordinator: Dan Octavian Alexandrescu, MD - Secretary of state, Ministry of Health

Technical Group:

- Adrian-Stelian Dumitru Ministry of Health
- Costin Iliuță Ministry of Health
- Simona Bădoi, MD NAMMD
- biol. Mirela Tavakol NAMMD
- Cristina Gavrilă, Ministry of Health NAMMD".

Art. II - This order is published in the Official Journal of Romania, Part I.

p. Minister of Health,Tiberius-Marius Brădăţan,Secretary of State