Saatja: Anne Poksi <Anne.Poksi@itk.ee>
Saadetud: 29.08.2024 10:51
Adressaat: <"Eda Lopato">; <"Johanna Liis Udumets">; <info@sm.ee>; <"Katrin Kiisk">; <info@ravimiamet.ee>
Koopia: Ilona Muoni - PERH <Ilona.Muoni@regionaalhaigla.ee>; Tiina Kärner <Tiina.Karner@kliinikum.ee>
Teema: FW: Your support needed at national level - Revision of the EU Pharma Legislation

Lugupeetud Eda Lopato
Lugupeetud Katrin Kiisk

Eesti Nukleaarmeditsiini seltsile (ENMS) on saabunud märgukiri Euroopa Nukleaarmeditsiini Assotsiatsiooni poliitika ja regulatiivküsimuste nõukogust (EANM Policy & Regulatory Affairs Council (PRAC)). Märgukirjas palutakse pöörata tähelepanu EL farmaatsiaalaste õigusaktide läbivaatamisel ka radiofarmatseutiliste preparaatide arvestatavale tähtsusele ja toetada riigisiseselt EANM muudatusettepanekuid EL ravimiseadustiku radiofarmaatsia osas.

EANM muudatusettepanekute eesmärkideks on tagada radiofarmatseutiliste ravimite kättesaadavus patsientidele vaatamata osakonnasisestele, haiglate vahelistele ja riikide vahelistele erisustele; ühtlustada regulatiivseid nõudeid kohapeal valmistatavatele radiofarmatseutilistele preparaatidele; selgitada juriidilisi nõudeid uudseid tehnoloogiaid pakkuvatele tootjatele.

Oleme ENMS juhatuses arutanud läbi EANM muudatusettepanekud (artiklites 4, 16 ja 142; lisatud manuses) ning nendega nõus.
Meie hinnangul ei muuda EANM muudatusettepanekud Eestis kehtivat radiofarmatseutiliste preparaatide valmistamisega seotud seadusandlust (Ravimiseadus ja sellest tulenevad määrused), vaid üldkokkuvõttes tagavad nukleaarmeditsiiniliste teenuste parema kättesaadavuse patsientidele radiofarmatseutiliste preparaatide valmistamise regulatiivsete nõuete ühtlustamise kaudu.

Teeme omalt poolt ettepaneku toetada riiklikul tasemel EANM muudatusettepanekuid EL nõukojas farmaatsiaalaste õigusaktide läbivaatamisel.

Oleme nõus vastama tekkivatele küsimustele ja teemat edasi arutama vastastikusel (virtuaalsel)kohtumisel.

Lugupidamisega, ENMS juhatuse nimel
Anne Poksi

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From: Amélie de Martini <> Sent: Thursday, August 1, 2024 11:24
AMCc: Silvia Marchetti <>Subject: Your support needed at national level - Revision of the EU Pharma Legislation

You don't often get email from .
Tähelepanu: E-kiri saadeti väljastpoolt Regionaalhaigla gruppi. Kui sa ei tunne saatjat või kahtled sisu ohutuses, siis ära ava linke ega manuseid!
Dear EANM National Delegates,

I hope this email finds you well.

I am contacting you on behalf of the EANM Policy & Regulatory Affairs Council (PRAC).

As you might know, although PRAC has recently achieved great milestones, there was a recent setback on the revision of the EU Pharmaceutical Legislation. Despite the dedicated efforts made by the EANM to advocate for the inclusion of radiopharmaceuticals and their specificities in the legislation, the European Parliament has recently rejected the proposed amendments. Now that the focus has shifted to the Council of the EU (i.e., Member States), PRAC is now increasing its outreaching efforts at the national level, to urge policymakers to reconsider.
For more information on the revision of the EU Pharmaceutical Legislation and the EANM views, I invite you to consult the following EANM statements (and).

To ensure that our efforts at the national level are as effective as possible, we would like to, please, ask for your support.

1. Should you have any relevant contact in your country (Health Ministry, Medicines Agencies or other regulatory bodies), we would very much appreciate if you could contact them to raise awareness on the importance of having radiopharmaceuticals considered within the revision of EU Pharmaceutical Legislation.
* To facilitate such an outreach, we have attached to this email a draft email which you could modify based on your needs and approach, as well as the most recent EANM statement and recommendations.

2. In our discussions with national points of contacts, we would like to make sure that we provide Member States´ specific information. Such information could include good practice related to regulation, but also potential impacts of a non-appropriate regulatory framework. Indeed, so far, PRAC has been able to detail the consequences of the current status quo with regards to EU Pharmaceutical Legislation at the European level, but not at the national level. Should you be interested to provide some details on potential consequences in your country, this would be very much appreciated.

Thank you very much in advance for your time and consideration.

Should you have any questions, please do not hesitate to reach out.

Kind regards,
Amelie

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Amélie de Martini
Head of EU Affairs

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