TRANSLATION FROM THE POLISH LANGUAGE

PRESIDENT

OF THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS

Warsaw, 02 September 2015

No. UR/DZ/0183/15

The National Centre for Nuclear Research
ul. Andrzeja Sołtana 7
05-400 Otwock

Digitally signed by Bolea Petru
Date: 2022.06.23 16:26:11 EEST
Reason: MoldSign Signature
Location: Moldova

DECISION

Pursuant to Article 155 in relation with Article 154 § 2 of Act of 14th June 1960 the Administrative Procedure Code (Journal of Laws of 2013, No. 267) and Article 35 of Act of 6th September 2001 –Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271, as amended)

it is decided to implement the following changes into the Marketing Authorisation No 22500 dated 12 June 2015 for the medicinal product Poltechnet, *Natrii Pertechnetatis (^{99m}Tc) fission formation solution iniectabilis*, radionuclide generator, 8.0-175 GBq on the name of Marketing Authorisation Holder:

Based on the law:
writing:

Pursuant to Article 7 section 2 in relation with Article 15 section 1 point 2 and pursuant to Article 18a section 4 of the Act of 6th September 2001 –Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271, as amended) is issued:

is replaced by the writing:

Pursuant to Article 7 section 2 in relation with Article 15 section 12 and pursuant to Article 18a section 4 of the Act of 6th September 2001 –Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271, as amended) is issued:

In section: “Frequency of periodic safety update reports submission”:
writing:

Not applicable

is replaced by the writing:

Pursuant to harmonized register of frequency of periodic safety update reports submissions settled based on Article 107c section 7 of Directive 2001/83/WE of the European Parliament and of the Council of 6 November 2001 on the Community code

relating to medicinal products for human use (Dz.U.L 311 of 28.11.2001, page 67, as amended).

SUBSTANTIATION

Pursuant to Article 155 of Act of 14th June 1960 the Administrative Procedure Code (Journal of Laws of 2013, No. 267) the final decision based on which a Party entered into rights, can be changed at any time if there is no other law and it is in the legitimate interest.

Change in the law and writing in point "Frequency of periodic safety update reports submission" results from the need of correct writing of the based law and the frequency of periodic safety update reports submission.

Registration dossier based on which the Decision No **UR/RD/0249/15** was issued on 12 June 2015 and was connected with Marketing Authorisation No **22500** for **Poltechnet**, Natrii Pertechnetatis (99mTc) fission formation solution iniectabilis, radionuclide generator, 8.0-175 GBq, contained data that are implemented into the MA by this Decision.

Marketing Authorisation Holder did agree for conducting this change based on the Article 155 Administrative Procedure Code.

Considering the above it is said like this.

Instruction:

Within 14 days of the date of service of this decision, pursuant to Article 127 § 3 and Article 129 § 2 of the Act of 14th June 1960 the Administrative Procedure Code (Journal of Laws of 2013, No. 267), the Party is entitled to file an appeal against this decision and submit thereof with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

A red round official seal with Poland's emblem, reading:
President of the Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products

A stamp, reading:
p.p. the President
VICEPRESIDENT
For Medicinal Products
/ - / *Signature illegible*
Marcin Kołakowski

Copies to:

1. The party's plenipotentiary
2. File copy