INSTRUCTION ON THE MANNER OF SUBMITTING APPLICATION AND DOCUMENTATION FOR SETTING/ALIGNMENT OF MAXIMUM PRICE OF A MEDICINE

For the purpose of setting maximum/alignment price of a medicine, marketing authorisation holders and wholesale authorisation holders shall submit the following documentation:

1. **Cover letter of the application for setting/alignment of maximum price (on the letterhead of the applicant):**

- Subject:
  - **Application for setting maximum price of a medicine** – medicines for which the maximum price is to be determined for the first time, or
  - **Application for alignment of maximum price of a medicine** – medicines for which the maximum price has already been set
- When submitting the application for alignment of maximum price, it is necessary to state the number of previous Decision
- Data on the applicant (name and headquarters of a legal person)
- Data on a medicine (ATC, INN, brand name, pharmaceutical form, strength, packaging)
- Information on the status of a medicine with regards to the procedure of issuance of marketing authorisation
  - If the medicine has been granted marketing authorisation, it is necessary to state the date and number of the CInMED Decision on placing the medicine onto the market
  - If the medicine has not been granted marketing authorisation, it is necessary to provide the information on its last import authorisation issued in accordance with the Article 5 of the Law on Medicines (number and date of CInMED import authorisation). If a marketing authorisation procedure has been initiated for a medicine in question at CInMED, please provide the procedure number and date. In addition to the requirements on this basis, it is necessary to submit a statement from the manufacturer of the medicine, or the marketing authorization holder in the EU on the type of medicine (whether the medicine has been authorized in the EU and/or the country of origin as an original, generic or biologically similar medicine). If possible, please submit a statement on the status of the medicine by one of the competent authorities of the countries where the medicine obtained the marketing authorization.
- Expert opinion on the status of the medicine (original/generic/biologically similar medicine)
- Date and signature of qualified person of the applicant

2. **Application form for setting maximum price of a medicine** [1]

When completing the application form - the following information sources should be used:

Republic of Serbia: Website of the Republic health insurance fund:

https://www.rfzo.rs/ Važeća lista lekova (Lists A, A1, B, C and D)

Please use the price from the column "I" - Wholesale price of the medicine for the packaging, converted into euros, using the middle exchange rate of the National Bank of Serbia on 1 February 2024.

[1] *Applications forms are available on the portal of the Institute: Legislation/Application form-medicines/Setting maximum prices of medicine/Application forms.*

Czech Republic: Website of the State Institute for Drug Control - SUKL:
www.sukl.eu – List of reimbursed medicinal products
Please use the final retail price from the column "CH" named **MFC**, multiplied by the correction factor 0.86 to get the wholesale price, converted into euros with the exchange rate published by the Central Bank of Montenegro for the Czech crown on 01 February 2024, as the date of the conversion.

Romania: Website of the Ministry of health of Romania:
www.ms.ro - Catalogul Public national al preturilor maximale ale medicamentelor de uz uman
Please use the price from the column "N"- **Preț ridicata maximal fără TVA (lei),** converted into euros with the exchange rate published by the Central Bank of Montenegro for the Romanian leu on 1 February 2024, as the date of the conversion.

The prices that were valid on 1 February 2024 are to be used as the source of the data from the reference countries on the price of medicines.

* In the event that it is not possible to determine a comparable price of a medicine in any of the publications from Article 6 paragraph 2, in addition to the application form and the application, it is also necessary to submit the following:

- evidence and data on EU Member States in which a medicine in question has been granted marketing authorisation and is present on the market
- evidence and information on the comparable price of a medicine in those countries

* As for prices of medicines derived from blood and human plasma, in addition to the Application form and the application, it is also necessary to submit the following:

- evidence and data on EU Member States in which the medicine in question has been granted marketing authorisation and is present on the market
- evidence and information on comparable price of a medicine in those countries
- evidence on the wholesale price calculation (CIP, customs costs and other incremental import costs, and wholesale costs)

Comparable wholesale price of a medicine in reference countries shall be calculated in the manner that the comparable wholesale price of a medicine in the currency in the reference country, or in the EU Member State is multiplied by the middle exchange rate of that currency against euro on the day of calculating, using the exchange rate of the Central Bank of Montenegro or the National Bank of Serbia, in case of the Republic of Serbia.

The application is submitted separately for each pharmaceutical form, strength and packaging of the medicine.
Applications for setting/alignment of maximum prices shall be submitted to the Registry office of CInMED.

Contact person for further information is Ms. Lidija Čizmović
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telephone: +382 20 310 280 (in the period from 12h to 15h)