

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

For the purpose of setting/alignment of maximum price of a medicinal product, 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
- In case that a medicine already has the maximum price set, and the application for alignment of maximum price is being submitted, it is necessary to provide the number of previously issued Decision issued by CInMED
- Data on the applicant (name and headquarters of a legal entity)
- Data on the medicine (ATC, INN, brand name, pharmaceutical form, strength, packaging)
- Information on the status of the medicine with regards to the procedure of issuance of marketing authorisation
 - If the medicine has been granted marketing authorisation, it is necessary to provide the date and number of the CInMED Decision on placing the medicine on 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 29 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 a responsible person of the applicant.

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

When completing the application form please use the following information sources:

Republic of Serbia: Website of the Republic Fund of Health Insurance:

www.rfzo.rs Važeca 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 the day of price calculation (provide the date of price calculation).

Czech Republic: Website of the State Institute for Drug Control - SUKL:

¹ Application forms are available on CInMED web portal: Legislation/Application form-medicines/Setting maximum prices of medicine/Application forms.

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

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 koruna (CZK) on the day of price calculation (provide the date of price calculation).

Romania: Website of the Ministry of Health of Romania:

www.ms.ro - Catalogul Public national al preturilor maxime 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 (RON) on the day of price calculation (provide the date of price calculation).

The prices valid on the date of the price calculation shall be used as the source data on medicine prices from the reference countries.

* In case that it is not possible to determine a comparable price of a medicine in any of the publications from Article 6 paragraph 2, of the Decree² in addition to the application form and the application, it is 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 the comparable price of the medicine in those countries.

* Regarding the prices of medicines derived from blood and human plasma, in addition to the application form and the application, it is 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 the 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 is calculated so 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 date of calculation, 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

e-mail: lidija.cizmovic@cinmed.me

Phone: +382 20 310 280 (from 12pm to 15pm)

² [Decree on the criteria of setting maximum prices of medicines](#) ("Official Gazette of Montenegro" br. 130/21 and 9/22, 20/24 and 113/25)