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/alignment of maximum price of a medicine.
* In case when a medicine has a maximum price already set, it is necessary to state the number of previous Decision
* Data on the applicant (name and headquarter of a legal person)
* Data on a medicine (ATC, INN, brand name, pharmaceutical form, strength, packaging)
* Information on the status of a medicine in regards to the procedure of issuance of marketing authorisation

- If a medicine has been granted marketing authorisation, date and number of the CInMED Decision on placing a medicine onto the market must be stated

- If a medicine has not been granted marketing authorisation, information on its last import authorisation issued in accordance with the Article 5 of the Law on Medicines must be stated (number and date of CInMED import authorisation). If a marketing authorisation procedure has been initiated for a medicine in question in CInMED, please provide the procedure number and date. In addition to 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 country of origin as an original, generic or biologically similar medicine). If possible, 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.

* Date and signature of responsible person of the applicant
1. **Application form for setting maximum price of a medicine[[1]](#footnote-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**](https://www.rfzo.rs)(Lists A, A1, B, C i D)

Republic of Croatia: Website of the Croatian health insurance fund:

[**https://hzzo.hr**](https://hzzo.hr) – (Basic and Additional List)

 Romania: Website of the Ministry of health of Romania:

[**https://www.ms.ro**](https://www.ms.ro) - Catalogul Public national al preturilor maximale ale medicamentelor de uz uman

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

* + evidence and data on in which EU Member States a 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

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

* + evidence and data on in which EU Member States 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 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 a manner that the comparable wholesale price of a medicine in the currency in the reference country, or in the European Union 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.

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

 telephone: +382 20 310 280 (in the period from 12h to 15h)

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