CInMED
Institut za ljekove i
medicinska sredstva Crne Gore

Regulation in practice: CInMED Interactive Workshop

Date: 9 September 2025
Duration: 9:00h - 16:00h
Venue: Ramada Hotel, Bulevar Save Kovačevića 74, Podgorica

AGENDA

8:30 - 9:00	Registration of participants
9:00 - 10:00	Preparation of the documentation for issuance of marketing authorisation for a medicine in accordance with regulatory requirements
10:00 - 10:45	Regulatory requirements and good practice in the preparation of the documentation for renewal of marketing authorisation for a medicine
10:45 - 11:00	Coffee break
11:00 - 11:30	Issuance of marketing authorisation under a fast-track procedure – CInMED experience
11:30 - 12:00	Procedure for notification and approval of multilingual packaging
12:00 - 12:30	Procedure for reporting and handling quality defects of medicines
12:30 - 13:30	Lunch break
13:30 - 14:00	Risk management plan and implementation of additional risk minimisation measures
14:00 - 14:45	Variations: preparation of the documentation, common concerns and latest regulatory trends
14:45 - 15:00	Coffee break
15:00 - 15:30	Marketing authorisation variations in the area of safety and efficacy data
15:30 - 16:00	Q&A

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