

## INSTRUCTION ON THE MANNER OF SENDING LETTERS TO HEALTHCARE PROFESSIONALS (DHPC)

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Letter to healthcare professionals (DHPC - Direct Healthcare Professional Communication) is important information for safe and effective use of a medicine, which may be sent to healthcare professionals either by marketing authorisation holder or by the Institute.

The responsible person of the marketing authorisation holder is obliged to regularly monitor the outcome of regulatory procedures carried out by competent authorities in the European Union (EU) regarding safety of the medicine which he is responsible for. In case that a decision to send letters to healthcare professionals has been made in the EU, the proposal of the letter to CInMED should be submitted simultaneously with the letter submitted in the EU countries, with the aim of informing relevant healthcare professionals in Montenegro in a timely manner.

In case that new information relevant to safe use of medicine refers to a medicine which marketing authorisation has been applied for/medicine marketed on the basis of import authorisation, the applicant/wholesaler that obtained import authorisation by the CInMED, is responsible for preparation of the letter proposal approved by the Institute and its distribution to healthcare professionals. The deadline for submission of letters to healthcare professionals, if submitted upon the request of the Institute, is seven days from the request. In exceptional circumstances, that period may be shorter.

When sending Letters to healthcare professionals, please ensure that the instructions listed below are followed:

1. **Proposal** of the DHPC may be submitted to the Institute (on a CD, as a Word document) or via e-mail (as a Word document). In both cases, the proposal obtains its reference number.
2. **Proposal of the Plan for Communication with Healthcare Professionals** should be attached to the DHPC and it should contain information on healthcare professionals/health institution which the Letter will be sent to, planned date and manner of communication.
3. In the event that several marketing authorization holders prepare a **joint letter**, the letter proposal and the plan for communication proposal shall be submitted to CInMED by one of marketing authorisation holders. In this case, a joint plan for communication proposal shall contain a clear information for each marketing authorization holder on which group of recipients the letter will be distributed to, when and in what manner.
4. Proposal of the DHPC and Plan for Communication should be accompanied by **cover letter** stating that proposal of the DHPC is in question and the exact name of a medicine that the DHPC refers to.
5. Harmonised versions of the DHPC (printed in colour and signed by a person responsible for pharmacovigilance in Montenegro) and the Plan for Communication should be submitted to the Office of the Institute in paper form, after obtaining approval for their contents by the Institute. In case of absence of the responsible person, the letter may also be signed by the back-up of the responsible person, if the data on the appointment of the back-up person were previously submitted to the CInMED. The DHPC and the Plan should be accompanied by cover letter stating that approved DHPC is in question, with reference number of the proposal of the DHPC.

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6. If the letter that relates to safety information is submitted in person or via the Post, then the front page of the envelope should be **marked by the label** designed by CInMED, with the aim of bringing contents of the letters closer to healthcare professionals' attention. Before sending, the label should be printed on, or stuck to the front page of the envelope. The label (size: 7,6cm x 5,6cm, in red colour) is available [here](#)