



Joint EU-MNE Programme for  
Employment, Education and Social Welfare



CInMED

Institute for Medicines and  
Medical Devices of Montenegro

# DISSEMINATION STRATEGY AND EXPLOITATION PLAN

Monitoring the prescription of diclofenac  
with the aim of optimisation  
of its safe use

*CFCU/MNE/128*

November, 2022.



This project is co-funded by  
the European Union



The project is implemented by



Joint EU-MNE Programme for  
Employment, Education and Social Welfare



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## List of Abbreviations

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<b>C&amp;VP</b>	<b><i>Communication and Visibility Plan</i></b>
<b>EU</b>	<b><i>European Union</i></b>
<b>PHC</b>	<b><i>Primary Health Care</i></b>
<b>IT</b>	<b><i>Information Technology</i></b>
<b>IIHS</b>	<b><i>Integral Information Healthcare System</i></b>
<b>HCP</b>	<b><i>Healthcare Professionals</i></b>
<b>HCI</b>	<b><i>Healthcare Institutions</i></b>
<b>CInMED</b>	<b><i>Institute for Medicines and Medical Devices</i></b>
<b>MoH</b>	<b><i>Ministry of Health</i></b>
<b>HIF</b>	<b><i>Health Insurance Fund</i></b>





## Table of Contents

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1. PROJECT DESCRIPTION.....	4
2. GENERAL DISSEMINATION STRATEGY .....	5
2.1 Overall and Specific dissemination objectives .....	5
2.2 Target Groups .....	5
3. DISSEMINATION ACTIVITIES AND TOOLS.....	7
3.1 Project web site .....	7
3.2 Promotional materials (brochures, leaflets, flyers...) .....	9
3.3 Project events .....	10
3.4 Publication of two scientific articles in relevant scientific journals .....	18
4. RESOURCES .....	18
4.1. Human resources.....	18
4.2. Financial resources .....	19
5. DETAILED ACTIVITY PLAN.....	20
6. EXPLOITATION PLAN .....	22
6.1. Key exploitable results.....	22
6.2. The barriers and risks for exploitation .....	22
6.3 The roles and responsibilities of project partners.....	23
6.4 The results of the project and real needs in relevant health sector .....	24
6.5 The results of the project and public policy making .....	24





## 1. PROJECT DESCRIPTION

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This project refers to monitoring the prescription of diclofenac and optimization of its safe use in PHC institutions, through innovative Information Technology (IT) solutions, with a scientific analysis, evaluation and publication of obtained data. By upgrading existing IT solutions into an Integral Information Healthcare System (IIHS) and creating new ones, scientific research in the field of rational use of medicines will be strengthened and thus contribute to improvement of health of people and society as a whole. In order to achieve defined goals and objectives, the activities covered by this project include activities related to implementation but also activities related to continuous support, in terms of project management and dissemination of project results to target groups and final beneficiaries. The Scientific community will also be involved through preparation of scientific articles for publishing in relevant scientific journals. For this reason, two work packages (WP) exclusively refers to overall project management activities and dissemination activities, while the remaining work packages refer to the implementation of different types of activities.

These implementation activities encompasses scientific analysis and comparison of data on the prescription of diclofenac before and after, by innovative IT solutions imposed restrictions in its use. These activities will be performing with the aim to achieve the expected results and finally the expected impact of the project.

**The expected results** of the project:

**Result 1.** Engagement of young and experienced researchers to scientific analyze the observed problem of nonrational use of diclofenac, which will improve scientific potential and visibility of CInMED in the domain of rational use of medicines.

**Result 2.** Development of innovative IT solutions, thanks to which the prescribing and use of diclofenac is going to be optimized.

**Result 3.** Improvement and better integration of Information System (IS) of CInMED and PHC.

**Result 4.** Optimising the prescription and consumption of diclofenac in PHC institutions in Montenegro.

**Result 5.** Harmonizing the prescription of diclofenac in PHC institutions with CInMED evidence based recommendations.

**Impact** - The strengthening of synergy between science and innovation, stimulating research and development of science, cooperation between the public and the private sector in improvement of human health and finally improvement of visibility and importance of CInMED in Montenegrin health and scientific community.





## 2. GENERAL DISSEMINATION STRATEGY

### 2.1 Overall and Specific dissemination objectives

**Overall dissemination objective** is to raise awareness among defined target groups and final beneficiaries (scientific and IT communities, patients, HCPs, creators of health policy) on rational use of medicines and importance of synergy between science and innovation (IT solutions) for that purpose.

**Specific dissemination objectives includes:**

- promotion of intermediate and final project results to key target group and final beneficiaries with focus on HCPs in PHC as prescribers of diclofenac
- publishing of obtained results in relevant scientific journals after thorough scientific analysis of obtained data on diclofenac prescribing
- delivering of key messages (recommendations) on diclofenac rational use through IS that HCPs use in they daily work.

### 2.2 Target Groups

In order to promote results of the project, a range of dissemination activities, focused on different target audience is going to be established. Priority target groups of the project are patients, HCPs and HCIs, CInMED (Coordinator on project) and MG Soft as project partner.

1. **Patients** and their health are the centre of every health system and society as a whole. The realization of the project and dissemination of its results is in the interest of all patients who are on the treatment with diclofenac and especially those patients who are due to comorbidities, medicines taken concomitantly with diclofenac, at high risk of serious adverse reactions; Prescribing of diclofenac in accordance with the latest scientific data will finally improve their health.
2. **HCPs and HCIs** in PHC owing to innovative IT solutions, will have key recommendations for safe and effective prescription of diclofenac in IT system they use in daily work; These IT solutions will decrease their workload and give more time to communicate with patients
3. **CInMED** will gain insight into reasons for nonrational consumption of diclofenac and be able to propose new measures to rationalize use of this medicine. CInMED will also strengthen its scientific potential in the domain of the rational use of medicines;
4. **MGSOFT** as leading national company in healthcare IT systems, will benefit with: (i) increased knowledge and expertise in developing DataWarehouse and





Business Intelligence tools; (ii) improvement of in house developed Healthcare IS for Montenegro; (iii) implemented innovative services/applications which significantly spread the experience and expertise within the company;

- 5. Governmental institutions (MoH, HIF) and society as a whole** are final beneficiaries of this project. MoH, institution that is responsible for determining measures for rational use of medicines may owing to results of this project introduce changes in national policies and regulations dealing with rational use of medicines. Development of IT system for monitoring of prescribing practice of diclofenac and in the future other medicines of public health interest, can contribute to their rational use thus leading to the more optimal use of limited financial resources at disposal of HIF.

- 6. Scientific research community (Montenegrin and global)**

CInMED is a scientific institution licenced for carrying out scientific and research activities in the fields of medical sciences and interdisciplinary research.

As fundamental activities in this project presume scientific analysis and comparison of data on the prescription of diclofenac before and after, by innovative solutions imposed restrictions in prescribing of diclofenac and preparational activities for publication of these data in relevant scientific journals, scientific research community, Montenegrin and global will be reached out.

This will contribute improved visibility and importance of CInMED in Montenegrin scientific community.





## 3. DISSEMINATION ACTIVITIES AND TOOLS

Dissemination activities has been ongoing throughout the project, as planned, in order to achieve maximum impact of the project. These activities include the following:

### 3.1 Project web site

In accordance with the dissemination plan, project website is launched in June 2020. The project website can be accessed directly through [this link](#) or indirectly through the CInMED (project coordinator) website.



This project is intended to strengthen the scientific and research activity of CInMED in the field of rational use of medicines, on the example of diclofenac, by creating innovative IT solutions to monitor the prescription of diclofenac in the Primary Health Care (PHC) and reduce its prescribing to patients at risk of developing serious adverse reactions, with unfavorable outcomes for their health.

Institute for Medicines and Medical Devices (CInMED) together with its project partner MG SOFT is one of the 13 grant beneficiaries awarded under the EU pre-accession assistance program to Montenegro (IPA II) "Collaborative grant scheme for innovative project ideas". The project primarily addresses the following thematic priorities, defined by the call for proposals: Medicine and health of people and Information and communication technologies. As the realization of the project will include scientific analysis of data, their publication in relevant scientific journals as well as education of the expert public (health care professionals) the project also addresses the thematic priority Science, education and identity. More information is available on the website of the Ministry of science, under the following [link](#).

### Project goals

1. Engagement of young and experienced researchers to scientific analyze the observed problem of nonrational use of diclofenac, which will improve scientific potential and visibility of CInMED in the domain of rational use of medicines,
2. Development of innovative IT solutions, thanks to which the prescribing and use of diclofenac is going to be optimized,
3. Improvement and better integration of Information System (IS) of CInMED and PHC,

### Project website

On 1<sup>st</sup> of December 2022 CInMED has introduced the new web site, so the new position of the Project web site link on new CInMED's site is given below:

#### News

01.04.2021

Monitoring visit and support for preparation of interim report and OTSC

Monitoring was conducted by MS. Ivana Staljetović from ICE (International Consulting Expertise) and Ms. Snežana Vukotić from Ministry of Education, Science and Culture of Montenegro. [Read more](#)

15.03.2021

Forth coordination meeting

Current realisation of project activities were considered and new project activities were discussed. [Read more](#)

05.02.2021







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Institut za lijekove  
i medicinska sredstva Crne Gore

O CInMED-u Novosti Regulatoriva Cjenovnik Servis za klijente Kontakt Predsjednički izbori 2023

Pretraži...



## O CInMED-u

Home » O CInMED-u

01

### Djelatnost

Institut za lijekove i medicinska sredstva je nezavisan regulatorni organ Crne Gore u oblasti lijekova i medicinskih sredstava

02

### Misija i Vizija

Misija Instituta je obezbjeđivanje kvalitetnih, bezbjednih i efikasnih lijekova i medicinskih sredstava odgovarajućih performansi

03

### Organizacija

Organi upravljanja Instituta su Upravni odbor i direktor

04

### Dokumenta

Opšti akti i druga dokumenta od značaja za poslovanje Instituta

05

### Sistem menadžmenta kvalitetom

Institut kontinuirano radi na implementaciji i unapređenju sistema kvaliteta

06

### Stručna mišljenja i CPP

Institut izdaje stručna mišljenja iz svojih nadležnosti

07

### Međunarodna saradnja

Institut se pozicionirao kao relevantan partner u regionu, Evropskoj uniji i međunarodnoj zajednici

08

### Reklamacije

U slučaju bilo kakve neusaglašenosti ili greške možete podnijeti reklamaciju radi ispravke



Institut za lijekove  
i medicinska sredstva Crne Gore

O CInMED-u Novosti Regulatoriva Cjenovnik Servis za klijente Kontakt

## Međunarodna saradnja

Home » O CInMED-u » Međunarodna saradnja



### Projekti

Institut će učestvovati u svim projektima od značaja za unapređenje nacionalnog zakonodavstva, regulative i procedura, kao i u naučno-istraživačkim projektima u kojima ima mogućnost da da svoj pun doprinos i iskoristi sopstvene kapacitete kao inovativna i naučno-istraživačka organizacija.

[TWINNING projekat](#)

[MEDI-THEFT projekat](#)

[Praćenje propisivanja diklofenaka u cilju optimizacije njegove bezbjedne primjene](#)



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This web site comply with the criteria for appropriate communication and visibility set out in *Communication and Visibility in EU-financed external actions Manual* and all visibility requirements are implemented according to the Grant contract and its Annex 2. The EU emblem accompanied by text acknowledging the Union's support is prominently featured. Project web site promote the project, its results and finally impact to expert (HCPs) and general audience (patients) as key target groups and to final beneficiaries as well. All relevant information about the project (objectives, information, news, event announcements, public reports, analysis...) are published on the project web site.

### 3.2 Promotional materials (brochures, leaflets, flyers...)

Different kind of promotional materials with the brief description of project results and generally project objectives has been designed and distributed to the representative of the target audience and final beneficiaries.

The promotional materials has been distributed at events – workshops.

During september 2021, the CInMED project team has been prepared the brochure and flyer for workshop that should be held to healthcare professionals in PHC regarding the project and messages/warnings that should be implemented in information system that will appear when prescribing Diclofenac. Both, brochure and flyer, has been approved from CFCU regarding visibility elements and both has been published in amount of 100 pieces and distributed to PHC centers as the second workshop has been organized on-line due to pandemic.



*Brochure and Flyer, September 2021*





In October 2022, the CInMED project team has been prepared the brochure and flyer for workshop that has been held to healthcare professionals in PHC regarding the project and the results of the messages/warnings implemented in information system that appear when prescribing Diclofenac. Both, brochure and flyer, has been published in amount of 100 pieces and distributed to PHC centers as the second workshop has been organized on-line due to pandemic.



*Brochure and Flyer, October 2022*

### 3.3 Project events

Two internal workshops has been held by MG Soft for CInMED employees. First workshop was organized in order to train CInMED employees for usage of DW and BI tools, delivered in first phase of the project. Second workshop has included training for usage of the module for setup of rules in CInMED IS. Based of defined rules, doctors will receive appropriate messages and warnings in the process of prescribing medicines.

In order to raise awareness about importance of rational prescribing of medicines, and the benefits it can bring to the HCPs, patients and the society as a whole, there were organized two events-workshops gathering representatives of target groups and final beneficiaries. First workshop has been on occasion of presenting the results of the first phase of the project and the second one to present the final results of the project. Due to the COVID19 pandemic the first workshop for the healthcare professionals has been delayed.

In August 2020, as planned, two workshops were held for CInMED researchers. The workshops were held by representatives of the project partners and related to the

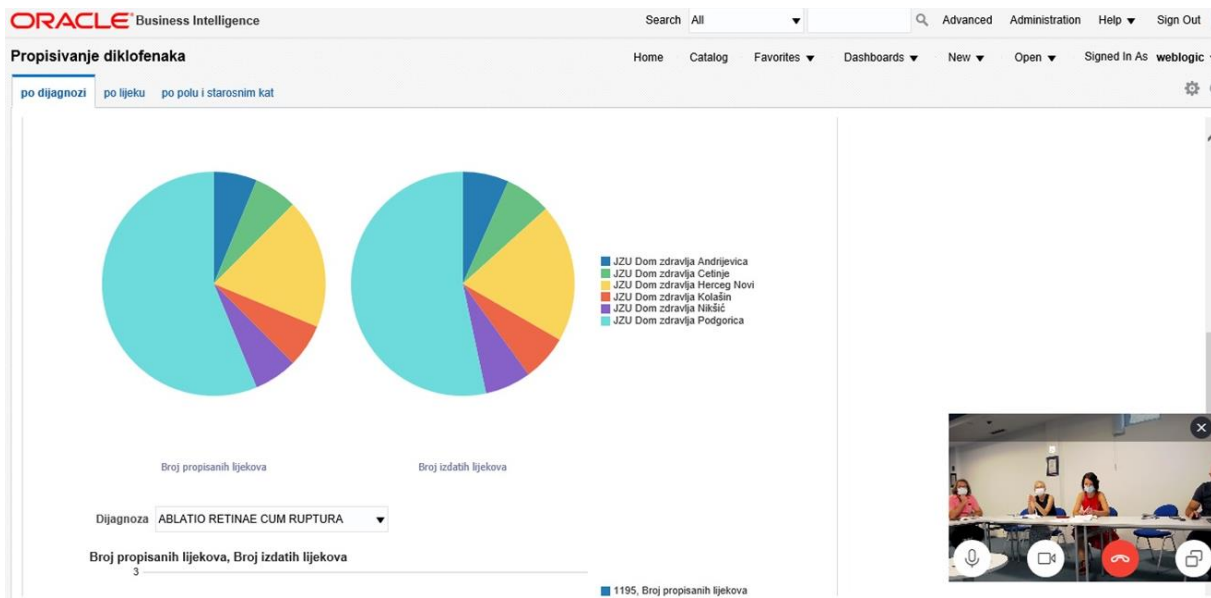




presentation of developed IT tools that will enable scientific analysis of data on prescribing diclofenac in Montenegro. Due to the complex epidemiological situation in Montenegro, the workshops were held through an *online* platform.



*Online meeting with participation of CInMED and project partner project team*



*Online meeting with participation of CInMED and project partner project team*





On 2<sup>nd</sup> October 2020 project goals and activities has been presented on the 10 minutes hosting on TV Vijesti Morning Show programme by Project manager Ms. Maja Stanković.

News was published on TV Vijesti web site on further link: <https://www.vijesti.me/tv/emisije/474139/gradjani-crne-gore-u-znacajnoj-mjeri-koriste-diklofenak-stankovic-alarmantne-vrijednosti> and also published on Youtube Link: <https://www.youtube.com/watch?v=yjhJ5vulctA>



## Građani Crne Gore u značajnoj mjeri koriste diklofenak, Stanković: Alarmantne vrijednosti

"Ako je vrijednost za dnevnu definisanu dozu na hiljadu stanovnika na dan, a to je ta osnovna statistička jedinica, u Crnoj Gori je preko 40. To znači da najmanje 40 stanovnika na 1.000 stanovnika u Crnoj Gori popije jedan diklofenak, dok u zemljama Evropske unije (EU) 10 do 15", rekla je farmaceutkinja Maja Stanković

8884 pregleda 1 komentar(a)



Stanković, Foto: Screenshot/TV Vijesti

*News on web site of TV Vijesti*







On March 29<sup>th</sup> 2021, the Project Manager has been attended in the training *Advancing the quality of the research work* held by International Consulting Expertise (ICE).

On April 23 2021, the Project Manager and Project Coordinator with two other CInMED employees attended a training *Hands-on Support to GB's regarding Horizon Europe* program, held by International Consulting Expertise (ICE).

On June 24, 2021 Project team CInMED has been held the presentation of project to the representatives of Ministry of Health (MoH, one representative) and Health Insurance Fund (HIF, four representatives). Participants were introduced to the project from the aspect of organization, resources and the team that implements it as the project's basic assumptions and project goals. It was also pointed out the role of MoH and HIF in the further implementation of the project relates to the acceptance of the recommendations of the research team and the implementation of these recommendations in primary health care (PHC) information system trough messages/warnings to physicians that will appear when prescribing Diclofenac.



*Presentation of project to the representatives of  
Ministry of Health (MoH) and Health Insurance Fund (HIF)*

During september 2021, the CInMED project team has been prepared the brochure and flyer for workshop that should be held to healthcare professionals in PHC regarding the project and messages/warnings that should be implemented in information system that will appear when prescribing Diclofenac. Both, brochure and flyer, has been approved from CFCU regarding visibility elements and both has been published in amount of 100 pieces.





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On 1<sup>st</sup> October 2021 has been held the first Workshop for Healthcare professionals in PHC where the primary health care professionals has been introduced with Project in overall (Presentation of the Project " Monitoring the prescription of diclofenac with the aim of optimisation of its safe use"); regarding data of prescribing of diclofenac and Project objectives; and finally the plan for the implementation of warning messages in IS of PHC as the tool for them to rationalise prescribing of diclofenac and improve public and individual health.



On 4<sup>th</sup> October 2021, the messages/warnings that appear when prescribing Diclofenac has been implemented in Primary Health Care Information System (PHCIS). This activity has been realized in cooperation of CinMED, MG-Soft and Health Insurance Fund that govern the PHCIS. Implementation has been approved by Ministry of Health.





**Kontraindikacije!**

Dijagnosticovana kongestivna srčana insuficijencija (NYHA II-IV), ishemijska bolest srca, periferna arterijska bolest i/ili cerebrovaskularna bolest su **kontraindikacije** za propisivanje diklofenaka.

Šifra recepta	Vrsta	Tip	Br pon.	Datum	Dijagnoza	Lijek	Kol Spec.	Dat dok.	Br dok.	Ozn.	Os	Zam
	1	R	1	24.09.2021	E12.0	M01AB05013 Diklofenak tabl. 20 x 50 mg	1			100	DA	

### Kod propisivanja oralnih formulacija diklofenaka:

**Posebna upozorenja i mjere opreza!**

Pacijenti sa kongestivnom srčanom insuficijencijom (NYHA klasa I) i pacijenti koji imaju značajne faktore rizika za nastanak kardiovaskularnih događaja (npr. hipertenzija, hiperlipidemija, dijabetes melitus, pušenje) terapiju diklofenakom **treba da započnu tek nakon pažljive procjene**. Preporučena maksimalna dnevna doza je 150 mg. **Kod blažih slučajeva, kao i kod dugotrajne terapije, 75 do 100 mg dnevno je obično dovoljno**. Neželjena dejstva se mogu svesti na najmanju moguću mjeru korišćenjem najviše efektivne doze, u najkraćem vremenskom periodu, neophodnom za kontrolu simptoma.

Šifra recepta	Vrsta	Tip	Br pon.	Datum	Dijagnoza	Lijek	Kol Spec.	Dat dok.	Br dok.	Ozn.	Os	Zam
	1	R	1	24.09.2021	E11.0	M01AB05013 Diklofenak tabl. 20 x 50 mg	1			100	DA	

### Kod propisivanja rektalnih formulacija diklofenaka:

**Posebna upozorenja i mjere opreza!**

Pacijenti sa kongestivnom srčanom insuficijencijom (NYHA klasa I) i pacijenti koji imaju značajne faktore rizika za nastanak kardiovaskularnih događaja (npr. hipertenzija, hiperlipidemija, dijabetes melitus, pušenje) terapiju diklofenakom **treba da započnu tek nakon pažljive procjene**. Preporučena maksimalna dnevna doza je 150 mg. Neželjena dejstva se mogu svesti na najmanju moguću mjeru korišćenjem najviše efektivne doze, u najkraćem vremenskom periodu, neophodnom za kontrolu simptoma.

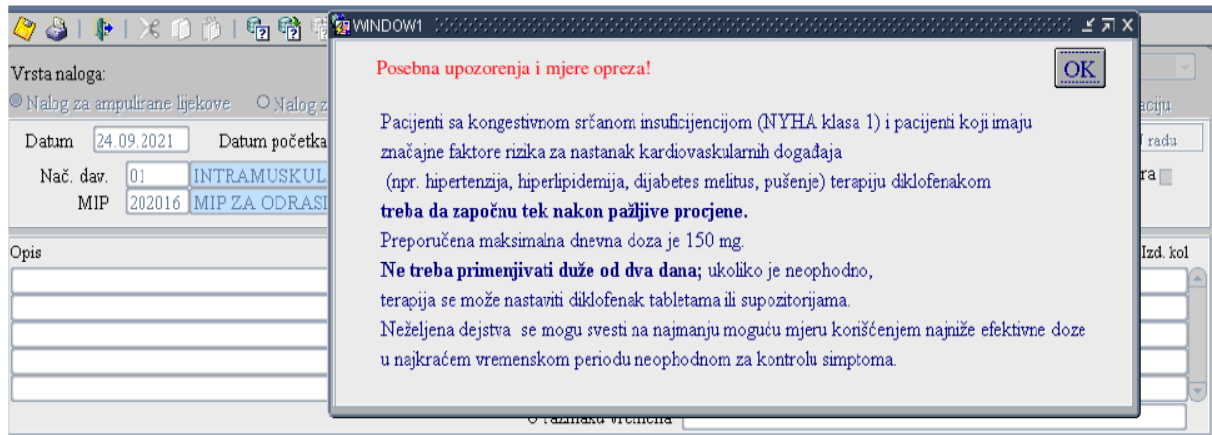
Šifra recepta	Vrsta	Tip	Br pon.	Datum	Dijagnoza	Lijek	Kol Spec.	Dat dok.	Br dok.	Ozn.	Os	Zam
	1	R	1	24.09.2021	E11.0	M01AB15020 Diklofenak supoz. 10 x 50 mg	1			100	DA	







### Kod propisivanja parenteralnih formulacija diklofenaka:



### *Messages and warnings implemented in Primary Health Care Information System*

All actions related to the notification of Primary Health Centers as well as individual doctors were taken over by the Health Insurance Fund, both through e-mail communication and by sending the notification's through the notification system that was developed in the primary health care information.

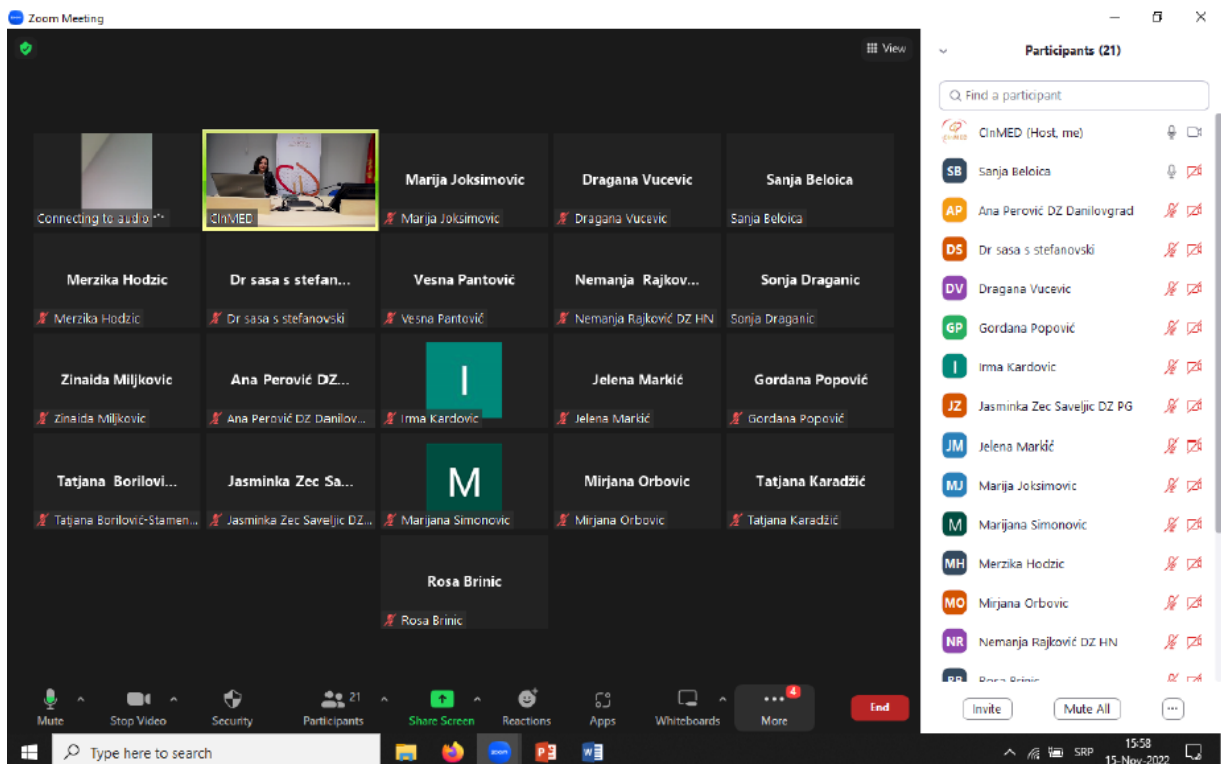
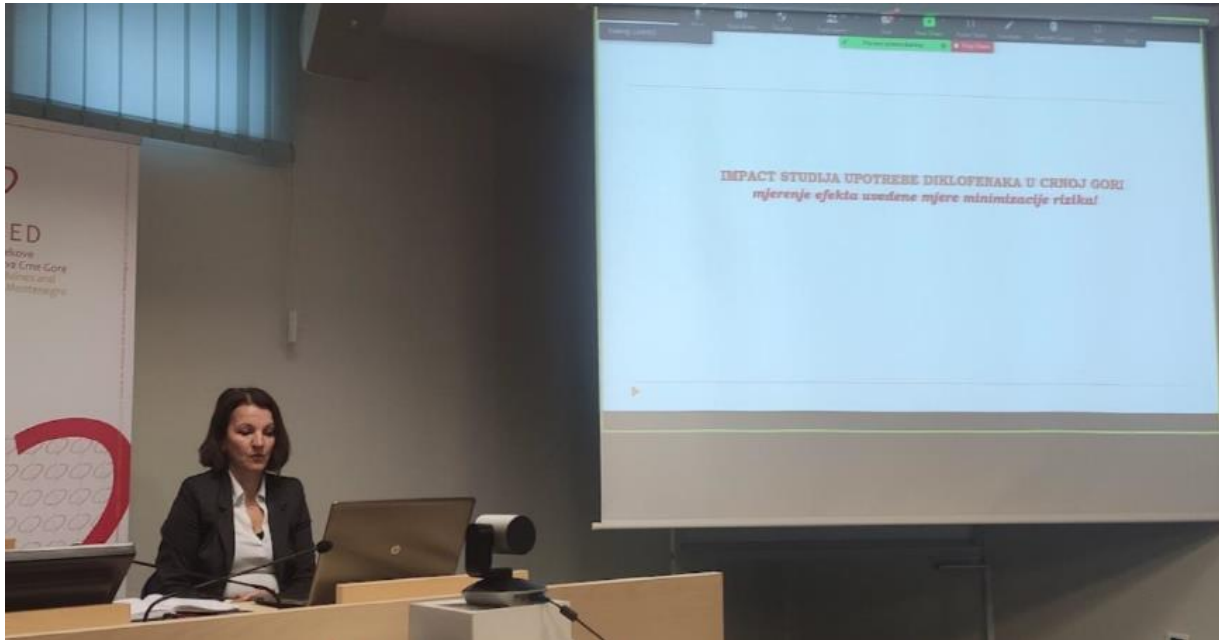
In October 2022, the CInMED project team has been prepared the brochure and flyer for workshop that has been held to healthcare professionals in PHC regarding the project and the results of the messages/warnings implemented in information system that appear when prescribing Diclofenac. Both, brochure and flyer, has been published in amount of 100 pieces.

On 15<sup>th</sup> November 2022 has been realised the second Workshop for Healthcare professionals in PHC where the primary health care professionals has been introduced with Project results after one year after the implementation of the messages/warnings that appear when prescribing Diclofenac in Primary Health Care Information System (PHCIS).





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All relevant information about the project are published on the project web site.



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### 3.4 Publication of two scientific articles in relevant scientific journals

This project has a strong scientific - research component. One of the most important and expected result of the project is preparation for publishing of two scientific articles in relevant scientific journals in biomedicine, based on scientific analysis of the data on prescription of diclofenac in PHC. This project will to the highest extent engage the scientific potential in coordinator with strong support of external experts to provide a high level of excellence in the scientific part of the project, its visibility and promotion to the health, scientific and wider community. Expertise in pharmacovigilance, pharmacoepidemiology, statistics, scientific evaluation of data on safety and efficacy of medicines, rational use of medicines and proposing of risk minimization measures, for both, internal and external experts is one of the main preconditions for successful implementation of the project.

The main role of coordinator researchers and experts in this project is to scientifically analyse and publish information obtained from the PHC information system, before and after the introduction of appropriate innovative IT by the project partner.

Upon Publishing of results of this project in scientific articles of relevance, the wider scientific community will be familiar with the activities that are the result of the synergy of science and innovation in order to rationalize the prescription of diclofenac in Montenegro

All project dissemination actions will be consistent with special conditions stipulated in Grant Contract and its relevant Annex, taking into considerations guidelines from Manual – Communication and Visibility in EU-financed external actions (01/01/2018)

## 4. RESOURCES

### 4.1. Human resources

Appropriate human and financial resources are foreseen for the implementation of the dissemination activities, envisaged by communication and visibility plan. These activities will be carried out by the coordinator in collaboration with the project partner. On behalf of coordinator: Project Manager–Maja Stanković and Project Coordinator - Denis Reković will act as Communication Managers. The same role on behalf of project partner will be assigned to Radovan Sekulić. Their engagement in dissemination activities is planned as follows:

1. Project web site creating and updating with relevant information (Denis Reković on behalf of coordinator and Radovan Sekulić on behalf of project partner)
2. Publication of two scientific articles in relevant scientific journals (Maja Stanković on behalf of coordinator)





3. Promotional materials and project events (Maja Stanković and Denis Reković on behalf of coordinator and Radovan Sekulić on behalf of project partner).

Full engagement of key people on the project for managing scientific, educational and promotional aspect of the project, will ensure that the appropriate working packages with the envisaged scientific/educational and promotional activities are implemented, in accordance with the deadlines and the planned budget.

## 4.2. Financial resources

Financial resources necessary for the implementation of project activities, including communication, are presented in the project budget.

COMMUNICATION AND VISIBILITY BUDGET OF THE PROJECT				
<i>Item</i>	<i>units</i>	<i>€/unit</i>	<i>cost €</i>	<i>Budget (Coordinator or Project partner)</i>
<b>Promotional material/Event</b>				
Leaflets	2.000	150,00	300,00	Project partner
Promo and dissemination materials for internal and external purpose	2	300,00	600,00	Project partner
Publications with data and analysis of the project results	2	250,00	500,00	Coordinator
Publish scientific journals	2	750,00	1500,00	Coordinator
Web-site development and maintenance	1	1800,00	1800,00	Coordinator/Project partner
Workshops for target groups	2	500,00	1000,00	Coordinator
Workshops for CInMED employees	1	1.140,00	1.140,00	Project partner
<b>TOTAL Coordinator (€)</b>				<b>3.000,00</b>
<b>TOTAL Project partner (€)</b>				<b>3.840,00</b>
<b>TOTAL BUDGET</b>				<b>6.840,00</b>





## 5. DETAILED ACTIVITY PLAN

Due to the COVID19 pandemic and in order to have enough time to collect data from PHC, make appropriate analysis and prepare scientific articles for publishing, the duration of the project has been extended for eight months.

Activity plan of the project <i>Monitoring the prescription of diclofenac with the optimisation of its safe use</i>							
March. 2021							
Activity	Why / target groups	Who	How	When	Financing Coordinator	Financing Project partner	Budget lines
<b>1. Activity group name (if applicable eg. Web-site related activities or promotional materials creation...)</b>							
Project web site	To promote project and disseminate its results/ Patients, HCPs, Final beneficiaries (MoH, HIF)	Coordinator / Project Partner	Project website will be linked on official website of Coordinator and Project partner. It will be contain all relevant information about the project (objectives, outputs-reports, analysis, publications, announcements and reports from the events)	2nd Quartal 2020 till the end of the project	MG Soft	MG Soft	5.8.1.
<b>2. Activity group name (if applicable)</b>							
Promotional materials	Key messages about project results and impact, in order to raise awareness/ Patients, HCPs, final beneficiaries (MoH, HIF)	Coordinator	On occasion of two workshops to be held during the project, promotional materials of different kind and content will be prepared.	3rd Quartal 2021 4th Quartal 2022	CInMED		5.1.2
User manuals and internal workshops promotional materials	Materials will be prepared for 2 workshops for CInMED employees	Project partner	On occasion of two internal workshops to be held during the project, user manuals and promotional materials of different kind and content will be prepared.	2nd Quartal 2020 (first internal workshop) 2nd Quartal 2021 (second internal workshop)	MG Soft	MG Soft	5.1.1 5.1.3





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**1. Activity group name (if applicable eg. Web-site related activities or promotional materials creation...)**

<i>Activity title</i>	<i>Name of the target group</i>	<i>Responsible body</i>	<i>Short description of activity and planed methodology for implementation</i>	<i>Date/period when is activity planed</i>	<i>xxx</i>	<i>xxx</i>	
Project events (workshops)	To promote intermediate (1st workshop) and final results of the project (2nd workshop) /Patients, HCPs, final beneficiaries (MoH, HIF)	Coordinator	Workshops with representative of key stakeholders engaged on project and representatives of final beneficiaries and target groups are great opportunity to disseminate project results, discussing, brainstorming and drafting new recommendations, guidelines.	1st Quartal of 2021 (first workshop) 4th Quartal of 2022 (second workshop)	CInMED		6.2.
Internal workshops	In order to train employees from CInMED, 2 internal workshops will be organized	Project partner	Workshops will cover usage of DW and BI tools, made available to CInMED employees during the project and usage of rules in CInMED IS in order to deliver messages and warning to doctors in PHC	2nd Quartal 2020 (first internal workshop) 2nd Quartal 2021 (second internal workshop)	MG Soft	MG Soft	6.1

**2. Activity group name (if applicable)**

Publication in scientific journals	To publish results in relevant scientific journals after scientific evaluation and analysis of data /Scientific Community, Final beneficiaries, HCPs	Coordinator	Engagement of young and experienced scientist and researchers prepare data for publication and finally their publication in relevant scientific journals	2nd Quartal of 2022 (first article) 4th Quartal of 2022 (second article)	CInMED		5.1.4.
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## 6. EXPLOITATION PLAN

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The main objective of this project is to optimise the use of diclofenac and ensure its safe prescription in PHC, through implementation of innovative IT solutions. Dissemination of projects results in accordance with the plan will ensure that potential of new knowledge and scientific findings can be exploited to the maximum. These objectives aim to increase the ability to best use of existing IT technologies and to develop new ones. This will be achieved through the specific objectives and activities detailed in the Annex I of the Grant Contract.

Effective exploitation plan of this project reflects the key exploitable results.

### 6.1. Key exploitable results

- **Knowledge**

Through engagement of young and experienced researchers and their scientific analysis of data on diclofenac prescribing, new knowledge on patterns of medicines prescribing will be generated. This knowledge is going to be further exploited for analysis of suspected non rational use of other public health significant medicines.

- **New Technologies**

Through development of innovative IT solutions and its implementation in PHC, prescribing of medicines will be optimised, with direct impact on public and individual patient health. Improvement and better integration of Information System (IS) of CInMED and PHC will be achieved.

- **New Methods** for rational prescribing of medicines will be considered. This will facilitate harmonizing the prescription of diclofenac in PHC institutions with CInMED evidence and science based recommendations.

- **Agreements** with institutions belongs to PHC on different area will be thoroughly considered

- **Networks** of CInMED with other scientific, innovative and health institutions in order to improve visibility and importance of CInMED in Montenegrin health and scientific community.

### 6.2. The barriers and risks for exploitation

The barriers and risks for exploitation (actual use of the results after project funding) are recognised and countered with appropriate measures:

- **Financial sustainability**







Board members of CInMED and MG SOFT will govern actively and effectively to guide the future of the software solution usage and ensure their long-term institutional usage in CInMED.

- **Institutional sustainability**

By transforming CInMED into the Institute for Medicines and Medical Devices (by the new Medicines Act) new scientific research body will be established. Capacity building of CInMED researchers in the domain of rational use of medicines through implementation of this project will contribute to further research in this very important public health activity. Agreements about cooperation in R&D activities between CInMED and MG SOFT will allow continuing development and maintenance of software products delivered in this project.

- **Policy level sustainability**

Adopting relevant guidelines, procedures, policies related to implementation of risk minimisation measures for medicines. Results of cross matching analysis will be used to improve guidelines by government institutions in accordance with EU recommendations.

### 6.3 The roles and responsibilities of project partners

CInMED, MGSoft and HIF are key stakeholders in this project, who in the preparation of the project held several meetings and consultations in order to adequately prepare the project proposal. CInMED was established by the Government of Montenegro by the Decision on Establishment of the Institute for Medicines and Medical Devices from 02 October 2008 ("Official Gazette of Montenegro" No 62/08). CInMED is a national regulatory body, i.e. expert and scientific institution with competences in the area of public health protection by assuring that quality, safe and effective medicines are present on the market. Among many competencies, providing information about medicines and proposing measures for their rational use is one of the core competency. Since its founding, the Institute in cooperation with local partner firm MG-Soft (project partner), has independently developed its own information system, which covers all business processes, some of them integrated into healthcare system. On the other side MG-Soft is a leading national company in healthcare IT systems. Successful realisation of envisaged project results for CInMED will mean insight in prescribing patterns of diclofenac in PHC. Based on this insight, results of the project will be exploited for optimal CInMED decision making related to risk minimisation measures of diclofenac prescribing by HCPs and finally use by patients.

Successful realisation of envisaged project results for MG SOFT (project partner) will mean improvement of MG Soft software products in healthcare.

Besides exploitation of project results by CInMED and MG SOFT and their own needs, these institutions will support exploitation of project results by other relevant institution







in healthcare system in Montenegro (HIF, MoH) which will finally have impact on patients health and improvement of society as a whole. This project at the same time can be a model for other countries for rational prescribing of medicines, as well as an example of cooperation between the regulatory Institute for medicines and the wider health system of the country in the mission of the protection of public health.

## 6.4 The results of the project and real needs in relevant health sector

In defining the scope of this project real needs in determining the causes of nonrational use of diclofenac in Montenegro were evaluated. These needs are of great relevance from health and economic perspective.

Diclofenac is a medicine significantly prescribed and consume in Montenegro. This is concluded based on analysis of annual reports on its consumption, which is prepared and published by CInMED. The value of its consumption is alarming compare to European union countries and when taking into account the safety profile of diclofenac, in terms of cardiovascular and gastrointestinal toxicity, especially after its chronic use, Taking into account above mentioned CInMED, as institution in charge of quality, safety and efficacy of medicines has informed healthcare professionals on new scientific, evidence based information on the safety profile of diclofenac, on two occasions, following the decision of the European Commission (EC) and the necessity of reducing the use of diclofenac in Montenegro. The first letter to the healthcare professionals in Montenegro on efficient and safe use of diclofenac was sent by CInMED in 2013, when the EC decision was adopted, and for the second time in 2015, Sending letters to health care professionals by CInMED, as a measure of minimizing the risk of use of systemic formulations of diclofenac (in analogy with measures implemented in the EU member states) in Montenegro, did not give the expected results. In order to propose new, more effective measure for rational use of diclofenac, the reasons for its nonrational use and generators of its consumption must be investigated. Taking into consideration the fact that diclofenac is prescription only medicine, with a high probability, it can be assumed that the reasons for its increased consumption is nonrational prescribing in PHC. This assumption was trigger in view of defining the scope of this project. It is expected that realisation of the project activities will give objective insight into the reasons for nonrational prescribing and consumption of this medicine in Montenegro.

## 6.5 The results of the project and public policy making

As non-rational use of diclofenac in certain patients is directly related to an increased risk of serious cardiovascular and gastrointestinal adverse reactions, the rationalization of its use is of public health relevance. This is especially important in the light of heavy burden of the population in Montenegro with cardiovascular

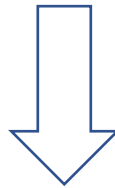




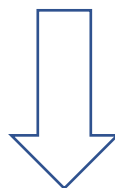
morbidity and mortality and the search for causes in possibly non-rational use of certain medicines, for which the nonrational use is associated with serious cardiovascular toxicity. Diclofenac is worldwide recognised as one of them.

In Master Plan of Health Development in Montenegro the basic goals and directions of the development of the health system in Montenegro, for the time period 2015-2020 are defined. In this document as one of the priority areas of organization and functioning of the health care system, the area of rational use of medicines has been recognized. Various analysis show that the doctor's attitude to prescribing is a key issue for effective but also rational pharmacotherapy. There is strong recommendation in this Plan that prescription analysis should be used in order to obtain objective information for decision makers in drug policy. Taking into consideration that based on innovative and scientific solutions, prescription of diclofenac analysis in PHC will be performed, CInMED and MG SOFT will, based on project results give recommendations and instructions for adopting/revising existing guidelines which refers to rational use of medicines.

***BETTER DISSEMINATION AND EXPLOITATION OF PROJECT RESULTS***



***MORE IMPACT ON SCIENTIFIC/ INNOVATIVE COMMUNITY AND WHOLE SOCIETY RESULTS***

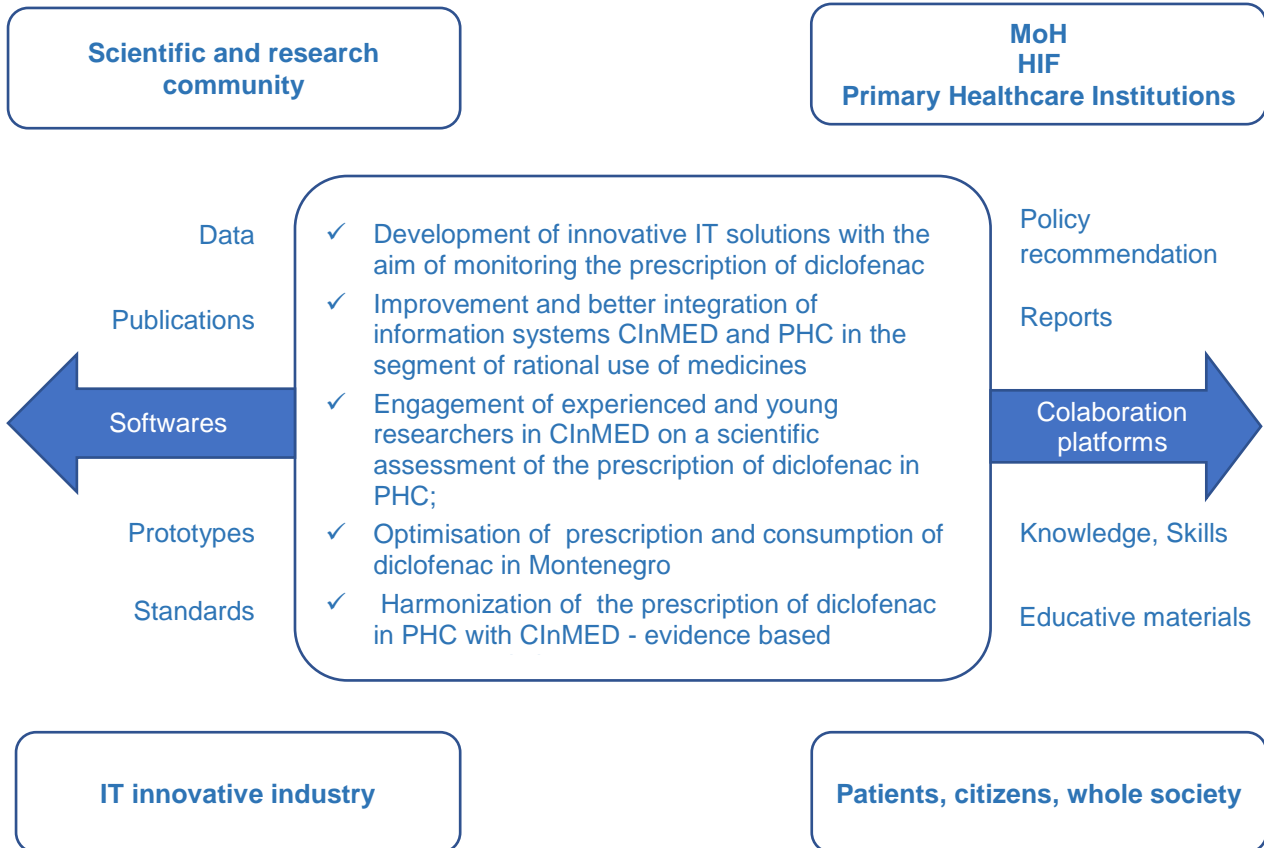


***IMPROVED VALUE OF FUNDING***





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## 7. UPDATES OF DISSEMINATION AND EXPLOITATION PLAN

This Dissemination and Exploitation Plan is not the final one. During implementation of this project project team consisted of representatives of coordinator and project partner will:

- update the plan according to the progress and emerging results of the project
- consider changes in the stakeholders, work context and potential use of results during the project lifetime and
- report on the updates periodically.



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