



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



CALIMS
Agencija za lijekove
i medicinska sredstva Crne Gore

DISSEMINATION STRATEGY AND EXPLOITATION PLAN

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

CFCU/MNE/128

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This project is co-funded by
the European Union



The project is implemented by



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



List of Abbreviations

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



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1. PROJECT DESCRIPTION

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 CALIMS 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 CALIMS 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 CALIMS 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 CALIMS 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, CALIMS (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. **CALIMS** will gain insight into reasons for nonrational consumption of diclofenac and be able to propose new measures to rationalize use of this medicine. CALIMS 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)**

CALIMS 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 CALIMS in Montenegrin scientific community.

3. DISSEMINATION ACTIVITIES AND TOOLS

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

1. Project web site

In accordance with the dissemination plan, project website is launched. The project website can be accessed directly or indirectly through the CALIMS (project coordinator) website.





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The screenshot shows the CALIMS website interface. At the top, there is a navigation bar with the CALIMS logo and the text "Agency for Medicines and Medical Devices of Montenegro". Below this is a horizontal menu with categories: Medicines, Medical Devices, Pharmacovigilance, Controlled Substances, Clinical Trials, and Manufacturing and Marketing. A left sidebar contains a list of menu items such as "About Agency", "Quality Management System", "Price List", "Legislation", "Public Procurement", "Expert Opinions", "Reports", "Publications", "Professional Meetings", "Cooperation", "Useful Links", "Contacts", and "eServices". The main content area features a large banner with the text "Adverse reactions reporting and sending messages on safe use of medicines via health information system". Below the banner is a "News" section with a list of articles. The first article is titled "COVID-19: Adverse Drug Reaction reporting" and is dated 15 September 2020. The second article is "The new Law on Medicines enters into force!" dated 06 August 2020. On the right side of the website, there is a search bar and several service buttons: "ONLINE ADR REPORTING", "ADR REPORTING FORM", "RAPID ALERT SYSTEM", "SIGNUP FOR NEWSLETTER", "FAQs", and "Monitoring the prescription of diclofenac with the aim of optimisation of its safe use". A blue arrow points to the last button.

CALIMS website www.calims.me

The graphic has a white background with a rounded border. At the top, the text "Monitoring the prescription of diclofenac with the aim of optimisation of its safe use" is written in a bold, red, sans-serif font. Below the text, there are three logos: the flag of Montenegro on the left, the logo of the Joint EU-MNE Programme for Employment, Education and Social Welfare in the center, and the flag of the European Union on the right.



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its safe use in PHC innovative IT solutions, scientific analysis, evaluation and publication of obtained data.

This project refers to monitoring the of diclofenac and optimization of institutions, through with a

CALIMS MG SOFT

This project is intended to strengthen the scientific and research activity of CALIMS 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. This project intends to harmonize the prescription of diclofenac in the PHC with evidence-based recommendations of CALIMS, which are in line with the recommendations of the European Medicines Agency (EMA) and formalized through the decision of European Commission (EC). Monitoring and reducing of diclofenac prescribing will be a model for monitoring the prescribing of other medicines, for which increased consumption indicates possible irrational use.

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 CALIMS 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 CALIMS and PHC.
4. Optimising the prescription and consumption of diclofenac in PHC institutions in Montenegro.
5. Harmonizing the prescription of diclofenac in PHC institutions with CALIMS evidence based recommendations.

News

16.06.2020
Data warehouse model delivered
Work Package 2 (WP2) report DEV 2.1 was delivered and published by the project partners. [Read more](#)

02.06.2020
Third coordination meeting
Third coordination meeting was held in premises of MG Soft. Creation of visual identity of the project and project website were discussed. [Read more](#)

30.04.2020
Second coordination meeting
Due to Covid-19 epidemic, second coordination meeting was held over Skype. Initial dataset for project Data Warehouse model were discussed. [Read more](#)

Project website

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.

2. Promotional materials (brochures, leaflets, flyers...)

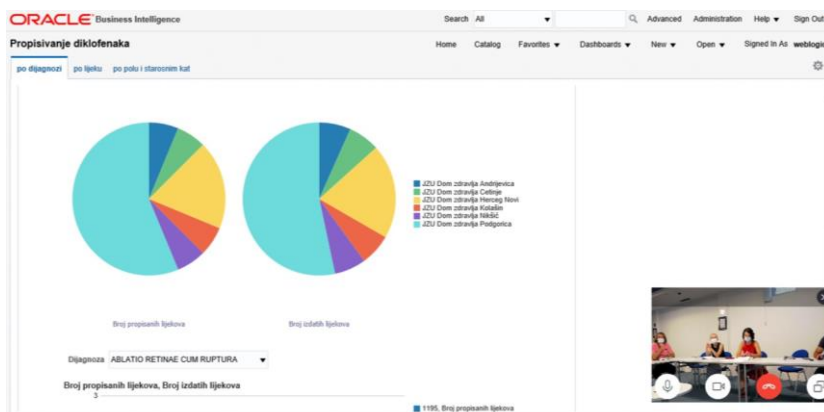
Different kind of promotional materials with the brief description of project results and generally project objectives will be designed and distributed to the representative of the target audience and final beneficiaries. The promotional materials will be distributed at events – workshops.

In August, as planned, two workshops were held for CALIMS 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 CALIMS and project partner project team



Online meeting with participation of CALIMS and project partner project team

3. Project events

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, it will be organized two events-workshops that will gather representative of target groups and final beneficiaries. First workshop will be 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. Two internal workshops will be held by MG Soft for CALIMS employees. First workshop was organized in order to train CALIMS employees for usage of DW and BI tools, delivered in first phase of the project. Second workshop will include training for usage





of the module for setup of rules in CALIMS IS. Based of defined rules, doctors will receive appropriate messages and warnings in the process of prescribing medicines. The workshops will be announced and promoted to expert and general audience by using general media tools i.e. articles in newspapers, publications on medicine and health, personal interviews, TV shows, etc.

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 publishing of two scientific articles in relevant international scientific journals, 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, 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.

Publishing of scientific results will be promoted on project website, to representatives of final beneficiaries and target groups as one of the most important topic on Agenda of workshops which will be organized during the project.

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

VISIBILITY BUDGET OF THE PROJECT				
<i>Item</i>	<i>units</i>	<i>€/unit</i>	<i>cost €</i>	<i>Budget (Coordinator or Project partner)</i>
Promotional material/Event				
Leaflets	2.000	150.00	300,00	Project partner
Promo and dissemination materials for internal and external purpose	2.00	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 CALIMS employees	2	1.140,00	2.280,00	Project partner
TOTAL Coordinator (€)				3.000,00
TOTAL Project partner (€)				4.980,00
TOTAL BUDGET				7.980,00





5. DETAILED ACTIVITY PLAN

Activity plan of the project <i>Monitoring the prescription of diclofenac with the optimisation of its safe use</i>							
April. 2020							
Activity	Why / target groups	Who	How	When	Financing Coordinator	Financing Project partner	Budget lines
1. Activity group name (if applicable eg. Web-site related activities or promotional materials creation...)							
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 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.
2. Activity group name (if applicable)							
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.	1st Quartal 2022	CALIMS		5.1.2
User manuals and internal workshops promotional materials	Materials will be prepared for 2 workshops for CALIMS 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





1. Activity group name (if applicable eg. Web-site related activities or promotional materials creation...)							
Activity title	Name of the target group	Responsible body	Short description of activity and planned methodology for implementation	Date/period when is activity planed	xxx	xxx	
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) 1st Quartal of 2022 (second workshop)	CALIMS		6.2.
Internal workshops	In order to train employees from CALIMS, 2 internal workshops will be organized	Project partner	Workshops will cover usage of DW and BI tools, made available to CALIMS employees during the project and usage of rules in CALIMS 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 analysi 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	1st Quartal of 2021 (first article) 1st Quartal of 2022 (second article)	CALIMS		5.1.4.





6. EXPLOITATION PLAN

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 CALIMS 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 CALIMS evidence and science based recommendations.

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

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

- **Institutional sustainability**

By transforming CALIMS into the Institute for Medicines and Medical Devices (by the new Medicines Act) new scientific research body will be established. Capacity building of CALIMS 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 CALIMS 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

CALIMS, 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. CALIMS was established by the Government of Montenegro by the Decision on Establishment of the Agency for Medicines and Medical Devices from 02 October 2008 (“Official Gazette of Montenegro” No 62/08). CALIMS 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 Agency 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 CALIMS will mean insight in prescribing patterns of diclofenac in PHC. Based on this insight, results of the project will be exploited for optimal CALIMS 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 CALIMS and MG SOFT and their own needs, these institutions will support exploitation of project results by other relevant institutions in the healthcare system in Montenegro (HIF, MoH) which will finally have an 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 agency 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 non-rational use of diclofenac in Montenegro were evaluated. These needs are of great relevance from health and economic perspectives.

Diclofenac is a medicine significantly prescribed and consumed in Montenegro. This is concluded based on analysis of annual reports on its consumption, which is prepared and published by CALIMS. The value of its consumption is alarming compared 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 the above-mentioned CALIMS, as an 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 healthcare professionals in Montenegro on efficient and safe use of diclofenac was sent by CALIMS in 2013, when the EC decision was adopted, and for the second time in 2015. Sending letters to healthcare professionals by CALIMS, 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 measures for rational use of diclofenac, the reasons for its non-rational use and generators of its consumption must be investigated. Taking into consideration the fact that diclofenac is a prescription-only medicine, with a high probability, it can be assumed that the reasons for its increased consumption are non-rational prescribing in PHC. This assumption was a 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 non-rational prescribing and consumption of this medicine in Montenegro.





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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 non-rational 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, CALIMS and MG SOFT will, based on project results give recommendations and instructions for adopting/revising existing guidelines which refers to rational use of medicines.



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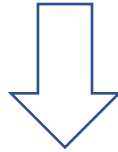
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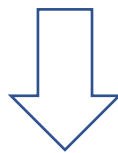
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BETTER DISSEMINATION AND EXPLOITATION OF PROJECT RESULTS



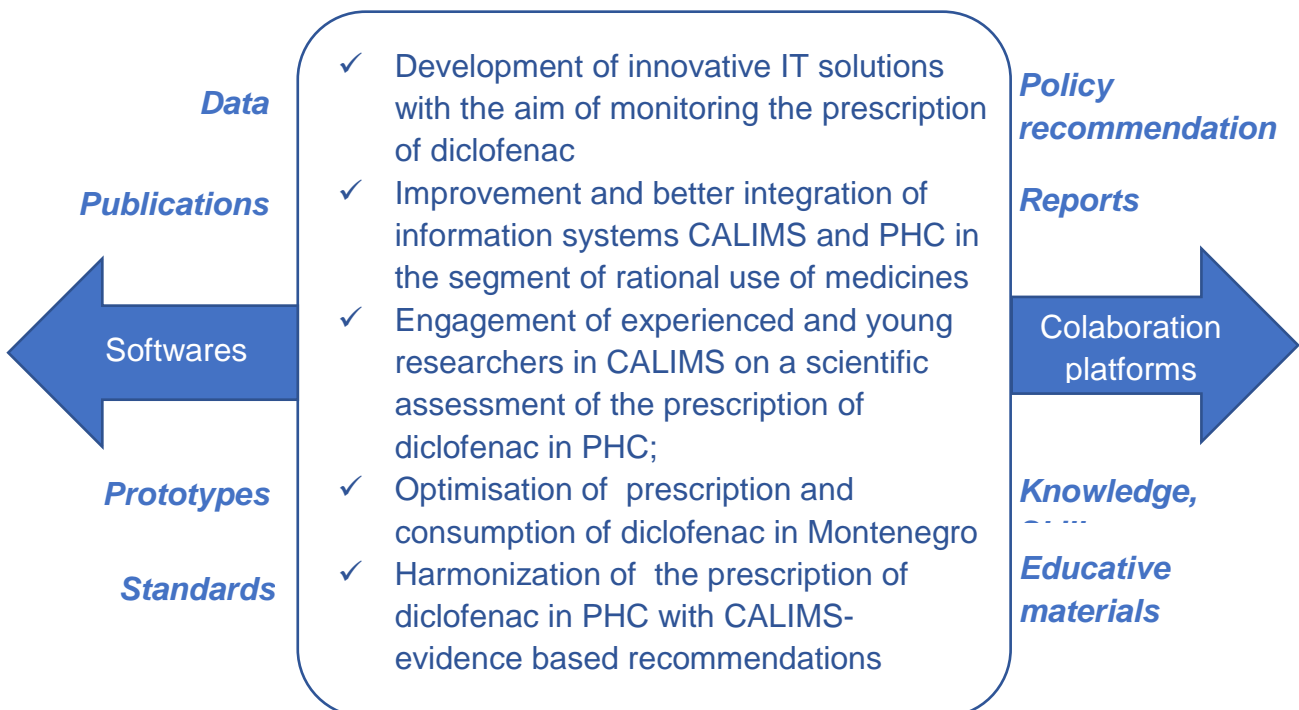
MORE IMPACT ON SCIENTIFIC/ INNOVATIVE COMMUNITY AND WHOLE SOCIETY



IMPROVED VALUE OF FUNDING

**Scientific and research
community**

**MoH
HIF
Primary Healthcare Institutions**



IT innovative industry

**Patients, citizens, whole
society**



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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.

