



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



WP6-RASING AWARENESS, DISSEMINATION AND BUILDING INNOVATIVE AND SCIENTIFIC CAPACITY

DEV 6.3 Building scientific and innovative capacities in CInMED and MG SOFT

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

CFCU/MNE/128

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List of Abbreviations

CInMED	<i>Institute for Medicines and Medical Devices of Montenegro</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>
HClS	<i>Healthcare Institutions</i>
MoH	<i>Ministry of Health</i>
HIF	<i>Health Insurance Fund</i>



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1. CInMED MISSION, VISSION AND STRUCTURE

CInMED's role is to actively contribute to the protection and promotion of public health through the regulation of medicines and medical devices. In line with the new Law on medicines ("Official Gazette of Montenegro" No. 80/20) CInMED is established as regulatory and scientific institution and internal organization of CInMED is organized in 6 divisions: Centre for medicines, Centre for medical devices, Centre for medicines post-marketing surveillance, Inspectorate, National control laboratory and Sector for economic, legal, IT and general affairs. Office of the managing director performs quality management, EU harmonization and international cooperation, as well as public relations affairs.

Since its establishment, CInMED has continuously strived to implement the highest European and international standards and achieve quality, impartiality and transparency in its work. New Law on Medicines extends the field of activity to scientific research. By the decision of the Ministry of Science No: 01-760/2 from April 21, 2017, the Institute was issued a license to perform scientific research activities in the field of medical sciences and interdisciplinary research.

By the decision of the Ministry of Science No: 03/2-051/20-1482/2 from September 9, 2020, it was determined that the Institute meets the conditions for performing innovation activities and it's entered in the Register of Innovative Organizations.

Mission

A mission of CInMED is to professionally and responsibly ensure presence of quality, safe, effective and rationally used medicines and medical devices and thus provide high quality of patient care in this field of health system.

An important segment of the mission of CInMED accordingly with the principles of good regulatory practice is to continuously improve the efficiency and transparency of business processes and thus ensure customer satisfaction.

Vision

The vision of CInMED, as highly-qualified, professional and independent institution, is to responsibly improve health care system functioning, especially the segments of registration and



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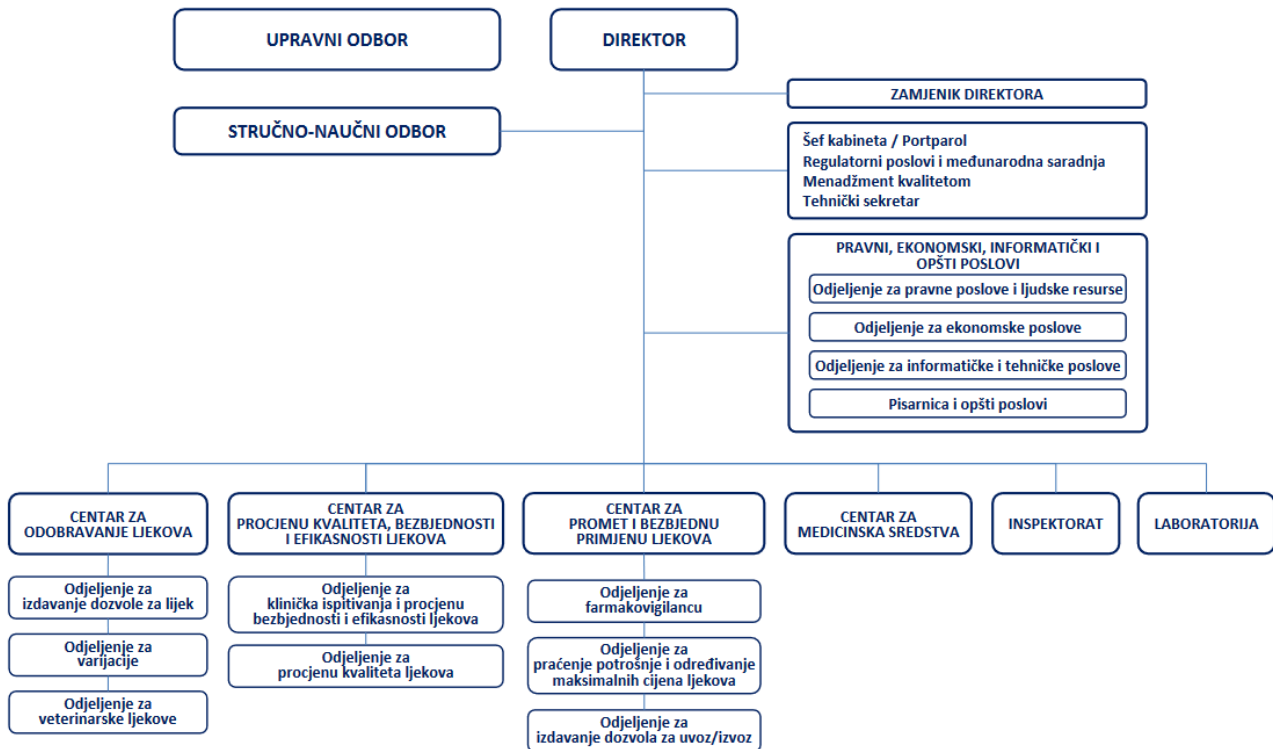
consumption of medicines, up to the standards of the European Union, and as such is recognized by patients, clients, authorities and experts in the area of medicines and medical devices.

Structure (from 03/2022)



ORGANIZACIONA STRUKTURA

Institut za lijekove i medicinska sredstva Crne Gore



Prilog 2 od 25.03.2022. godine

Figure 1 Organizational structure of CInMED



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2. SCIENTIFIC AND INNOVATIVE AREA OF BUSINESS

CInMED is a regulatory as well as a scientific research and innovation organization. The manufacturing and marketing of medicines is an activity of public interest and medicines must meet the highest standards in terms of quality, safety and efficiency, all in order to preserve the health of the individual and public health. The competence of CInMED of special importance for public health refers to pharmacovigilance, ie. monitoring the safety of medicines use. Modern IT are increasingly used to monitor the safety of medicines use. It is this innovative project for CInMED that represents the beginning of the use of information technologies in the rational prescribing of medicines.

Thanks to this project CInMED (previously known as CALIMS) met all criteria necessary to be registered as innovative institution, accordingly to Law on innovation (2020). Successful implementation of the project will strengthen the scientific research and innovation capacity of the institution and strengthen the impact of CInMED on the health system in Montenegro. It is to be expected that this will have positive health and economic impacts on the health system in Montenegro. The CInMED website (www.cinmed.me) contains numerous publications in the field of pharmacovigilance and drug consumption of importance to the professional and general public in Montenegro.

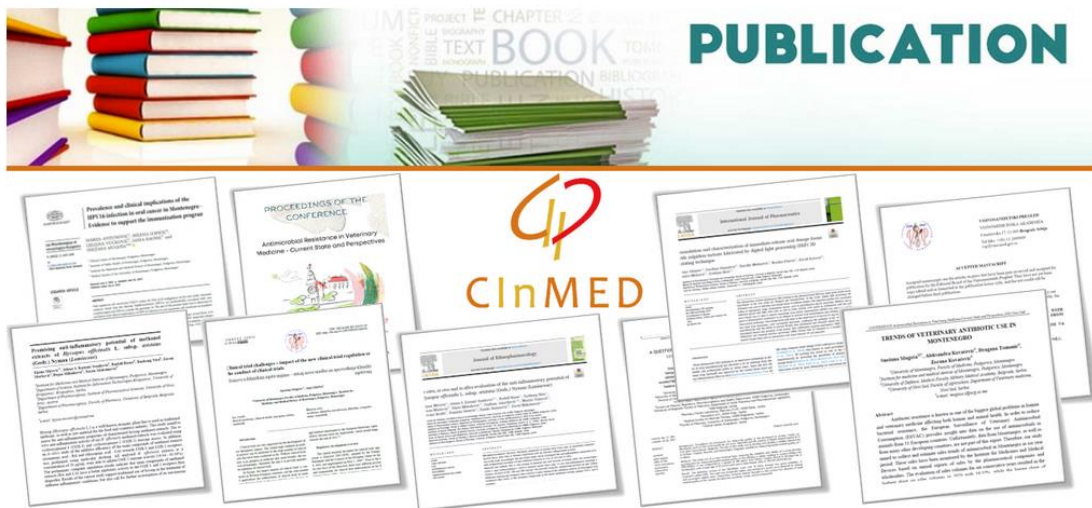


Figure 2 CInMED Publications



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During the implementation of this project, CInMED internal researchers, in collaboration with external researchers, analyzed data on the prescribing of diclofenac in PHC. Despite the fact that Montenegro has had a competent authority in the field of medicines and medical devices for almost 15 years, which continuously monitors the life cycle of all medicines, especially in the area of safety information and transmits them to healthcare professionals, implementation of CInMED recommendations in clinical practice is worryingly small. The effectiveness of the implemented risk minimization measures (*DHPC- Direct Healthcare Professional Communication*) for the use of diclofenac implemented by CInMED proved to be very low, taking into account the data on the consumption of diclofenac, which speak in favor of a continuous increase in its consumption. By analyzing the entry of medicines data into the PHC information system by PHC professionals, it can be concluded that the entry of drug data into IS PHC should be improved in order to make the analysis of prescribing data and conclusions in this regard more reliable. The progress of IT technics and its use in the analysis of medical data in the coming period will be a model for improving the role of CInMED in the protection of human health.

3. IT TECHNOLOGIES AS INNOVATIVE TOOLS IN HEALTHCARE

CInMED is an institution responsible for the quality, safety and efficacy of medicines and medical devices marketed in Montenegro. CInMED also participates in informing and educating about medicines and providing information to the professional and general public, which is important for the implementation of measures for the rational use of medicines. This information is based on evidence and a scientific assessment of the medicines documentation. The challenge is to make key information relevant to medicines prescribing understandable and accessible to healthcare professionals who dispense, administer, and prescribe medicines. This information should be made available to healthcare professionals in a concise form so that they can make the best possible decision when prescribing medicine to the patient. This decision is determined not only by the characteristics of the medicines, but also by the characteristics of the patient, his accompanying medical conditions and other medicines that patient takes at the same time. The challenge of CInMED in communicating with healthcare professionals is how to make up-to-date information on the efficacy and primarily the risks of medicine use available to healthcare professionals. The use of innovative IT technologies is one of the solutions that can help in the rational prescribing of medicines and reducing the risk of their use. It is very important from the multitude of medical data for each patient to obtain adequate information on individual efficacy and tolerability, which may be not favorable to a particular patient, despite the fact that the benefit-risk balance of that medicine is favorable and positive and as such it is approved for use in Montenegro.



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4. COLLABORATION WITH HEALTHCARE INSTITUTIONS AND ACADEMIA

Connecting CInMED information systems with information system of HCIs can go a long way in preserving individual health and public health. The use of health data outside of controlled clinical trial conditions can significantly affect the course of their health outcomes. It is especially important to act preventively in terms of minimizing the risk of adverse effects of therapy, unwanted interactions and thus poor health outcomes through the timely identification of at-risk patients in connection with the prescribing of certain medicines. In the light of the latest definition of adverse reactions which is the subject of the Law on Medicines and at the same time harmonized with EU regulations that adverse reactions imply harmful and unintended effects of the medicine, regardless of the administered dose, it is very important to investigate and classify the use of certain medicine as approved - use in accordance with indications approved by CInMED, or perhaps as an use that is not in accordance with the approved use (off label), misuse of medicine or medication error.

5. GAINED EXPERIENCE AND LESSONS LEARNT

The innovative project "*Monitoring the prescription of diclofenac with the aim of optimisation of its safe use*" was an excellent opportunity for CInMED, as a very important institution in the health system, to gain valuable experience in the implementation of projects that are innovative and at the same time scientific and research. In the coming period, the plan is to initiate new innovative and scientific-research projects aimed at strengthening the capacities of CInMED in these areas and for the benefit of wider social communities.

At the same time it is well known that Montenegro is the first country outside the EU to adopt the Smart Specialization Strategy (S3) in June 2019.

Achieving the main goal of S3, i.e. a modernized and competitive Montenegro, is based on three key strategic directions that represent the general long-term vision of the country's development, namely: Health Montenegro, Sustainable Montenegro and Digitalized Montenegro. Among four different area of priority in S3 is Information and Communication Technology.

The successful implementation of this project has shown that Information and Communication Technologies are applicable in almost all CInMED competencies, which confirms the fact that CInMED together with domestic and international partners can be a strong participant in the innovation environment in Montenegro.





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6. CONCLUSIONS

CInMED, as the competent institution in Montenegro, since its establishment as the Agency for Medicines and Medical Devices, is becoming closer to the health care system thanks to among others IT tools. In this way, it can only contribute to the improvement of the health system by enabling the use of information on the actual use of medicines in practice and the use of that information in decision-making regarding the further status and possible restriction of medicine use. Numerous researches of the quality, safety and efficacy of medicines that precede their placing on the market are based on very strict and scientifically based guidelines which is a prerequisite for their placing on the market. However, the actual use of medicines, ie their use in clinical practice, can vary significantly from something that is evidence based and that can compromise the efficacy and safety of medicine. The implementation of IT tools can help to reduce such non rational use of medicines and harmonize their use with evidence based medicine which is the interest of CInMED, all institutions in the health system because it ultimately improves health and saves human and economic resources of each state.



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