HALMED

Agency for Medicinal Products
and Medical Devices of Croatia

QUALITY POLICY STATEMENT

The Agency for Medicinal Products and Medical Devices (HALMED) is a legal entity vested with public authority providing services pertaining to medicinal products, medical devices and veterinary medicinal products in accordance with the laws and bylaws. The founder of the Agency is the Republic of Croatia, and the legal compliance of the Agency's activities is supervised by the Ministry of Health.

On behalf of the Agency for Medicinal Products and Medical Devices, the Head of the Agency is adopting the following quality policy:

The Directorate of the Agency commits all organisational units to respecting the professional confidentiality and good professional practice and work quality that should be at the highest level when providing services, which is achieved through a permanent education in professional and scientific field, as well as through employees' support in acquiring new skills needed. therefore. The Agency will undertake measures that will contribute to a correct, confident and ethical execution of its work processes.

In order to ensure a high quality of its services, the Agency continuously builds upon and improves the quality management system under the following standards: HRN EN ISO 17025; HRN EN ISO 9001; HRN EN ISO 9004; HRN EN ISO 19011; HRN EN ISO 17020; HRN EN ISO 27001; HRN EN ISO 31000; HR ISO 45001; HRN EN ISO 14001 as well as the QA guidelines of the OMCL Network; EMA, WHO and PIC/S guidelines for GMP and PhV; and by benchmarking of the EU/EEA agencies - BEMA.

All employees in all organisational units of the Agency at all levels at their work, as well as in public appearances, must promote the Agency's quality policy and its values and continuously work to improve the quality management system.

In order to achieve a high quality level of the functioning in the integrated European regulatory area, the Agency will develop and strengthen its proper internal infrastructure, which implies human resources and an appropriate technical support, encouraging a permanent commitment in the implementation of the *acquis communautaire* and permanent harmonisation with changes in the European legislation in the field of medicinal products medical devices and veterinary medicinal products. In achieving this task, the Agency will develop a strong co-operation with national, European and international competent authorities for medicinal products, medical devices and veterinary medicinal products.

The Agency will continuously improve the transparency of the regulatory system and ensure the prompt availability of information encouraging the development of efficient procedures that will facilitate the access to the safest medicinal products, medical devices and veterinary medicinal products for Croatian citizens.

Zagreb, 28th October 2022

AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE 6 ZAGREB

Head of Agency

Prof. Siniša Tomić, PhD