

Joint Action EU4H-2021-JA-11

NAMMDR participates in EU4Health Joint Action EU4H 11

EU4H 11 (Joint Action on quality of medicines and implementation of the pharmaceutical legislation/strategy) is part of the EU4Health programme funded by the European Commission. The total budget of this Joint Action amounts to more than 3 million EUR, 80% of the costs will be co-financed by the European Commission.

The project aims at strengthening capacities of EU/EEA GMP/GDP inspectorates in the global vision of mutual reliance of inspection data to better ensure quality of medicinal products and protection of Public Health.

39 EU/EEA Medicines Inspectorates from a total of 29 EU/EEA countries are participating in EU4H11: they are supervising the regulatory compliance of pharmaceutical manufacturers of human and veterinary medicines throughout EU/EEA. The Joint Action is steered by Austria (AGES/BASG) as Coordinator, together with the National Competent Authorities of France (ANSM), Croatia (HALMED) and Hungary (NCPHP) as work package leaders.

The three main goals of EU4H 11 are:

- Strengthening the Joint Audit Programme (JAP) for EU/EEA GMP Inspectorates.
- Developing a proposal to include GDP to the existing Joint Audit Programme.
- Establishing harmonised training and qualification processes for GMP inspectors, in cooperation with the PIC/S Inspectorates' Academy.

In addition, the co-financing of costs related to JAP activities supports member states' participation in the JAP. The co-financing of costs related to training activities supports initial and continuous training of GMP inspectors, thus enhancing competences of GMP inspectors throughout EU/EEA.

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Website link for detailed information: https://www.ages.at/en/research/project-highlights/eu4h11

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