aRMM – Croatian experience on challenges for industry to overcome
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Additional risk minimisation measures pose a challenge to both industry and the regulators. Applicants are obliged to actively monitor safety profile of their medicinal product and to anticipate its important safety risks, based on their own experience or information already available for originator products licensed in the EU. Croatian legislation on pharmacovigilance was last updated around the time of accession to the EU. Any further update is presented through the publicly available news section on HALMED website. Especially news concerning nationally licensed medicinal product are obliging for MAHs for Croatia. Important safety information is usually first communicated to the HCPs via DHCPs and later on in aRMM, following particular country-specific protocols. Request for common aRMM assessments is strongly supported by HALMED, with educational materials on generic name, version and HALMED approval date inserted. Approval costs for the initial aRMM materials and their update is the same, with approval timelines from 6 months to 1.5 years with tendency to decrease. Preparation of common PASS/PAESS studies may be requested by the NCA, irrespective if the licensed medicinal product is marketed in Croatia. What can the industry do to decrease costs and enhance product safety?

Recent Publications

Biography
Kety Mirkovic Kos is a passionate multilingual pharmacovigilance and regulatory expert with comprehensive domestic and international work experience and 60+ completed courses and trainings in the fields of pharmacovigilance, regulatory affairs management, consultancy and quality assurance.

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