The evolution of drug regulatory sciences in the Netherlands: 15 years of follow-up

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Abstract

In the Netherlands drug regulatory science is a vibrant national and internationally oriented community. In this review we present the factors that have contributed to this successful collaboration between relevant stakeholders, and that led to a surge of activities around how regulatory science became embedded in the ecosystem of medicines research, clinical pharmacology, policy making and regulation. We distinguished three pivotal episodes: 1) TI Pharma Escher-project, 2) Dutch Medicines Evaluation Board as catalyst of the big jump, 3) Regulatory Science Network Netherlands and multistakeholder engagement. The research agenda has been influenced by the dynamic evolution of legal frameworks in Europe, such as the EU orphan medicines legislation of 2001 and the EU pharmacovigilance legislation of 2012. All these developments have inspired and have raised pertinent regulatory sciences questions. Furthermore, clinical pharmacology as a discipline has been very influential in shaping regulatory science, contributing to discussions on the level of clinical evidence that is necessary to justify marketing approval of a new medicine. With a growing interest of multiple parties such as academics, EMA, national agencies, patient organisations and EFPIA, connecting regulatory science activities is key.

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