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ISSN: 2329-6887
Journal of Pharmacovigilance

Opinion Article

Links between Uncertainties Identified by the European Medicines Agency

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DESCRIPTION

The European Medical Agencies (EMA) is the regulatory authority with jurisdiction over all Europe Union Member States (EUMS). It coordinates a network of approximately 4,000 pharmacovigilance professionals from EU and European Economic Area (EEA) regulatory authorities. Its activities include issuing guidelines to provide Marketing Authorization Holders (MAHs) and EU clinical trial sponsors with information on the safety, efficacy and quality of both human and veterinary medicines. The Committee for Medicinal Products for human use (CHMP) was established as the body to carry out all pharmacovigilance activities for medicinal products for human use on behalf of the EMA.

Unlike centralized procedures, individual EU member states can grant national marketing authorizations for medicines based on local assessments of quality, efficacy and safety. Companies may use such national authorizations as the basis for mutual recognition procedures. This country acts as a reference Member State and its ratings are assessed by other her EU Member States (the Member States concerned). Decentralized processes are similar and are mainly used for generic drugs. This includes synchronized submissions and subsequent evaluation by several EU member states.

The EMA's work benefits

1. Patients
2. Healthcare professionals
3. Academics
4. Pharmaceutical companies
5. Medicine developers
6. Health policymakers

Through its scientific guidelines, scientific advisory programs, and incentives, it facilitates research and encourages the development of new medicines, transforming medical advances into medicines with real health benefits for patients. In particular, we support the development of paediatric drugs and orphan drugs.

EMA functions as the European Union's decentralized scientific body (not a regulatory body) whose main task is to protect and promote human and animal health through the evaluation and supervision of human and veterinary medicines. More specifically, it coordinates the evaluation and monitoring of centrally approved products and country referrals, develops technical guidance, and provides scientific advice to sponsors.

EMA provides pharmaceutical companies with scientific advice to support research and development and general advice on complying with Community law. Companies pay administrative fees for these and other activities. Before a medical device can be used, it must undergo a series of tests to determine whether it meets legally mandated quality and safety requirements. This includes complex and time-consuming toxicological, pharmacological and clinical trials. Animal products must meet additional requirements to ensure that no residues are left in food produced by animals.

EMA has a 20 year track record of ensuring the efficacy and safety of human and veterinary medicines across Europe and promoting research and innovation in drug development. In the first 20 years, the FDA recommended approval of a total of 975 human drugs and 188 veterinary drugs. The EMA's success is based on collaboration within the European Medicines Regulatory Network (EMRN). This is a unique partnership between the European Commission, the European Economic Area countries' pharmaceutical regulatory authorities and the EMA. This collaboration facilitated the exchange of knowledge, ideas and best practices to ensure the highest standards of pharmaceutical regulation.

Seven EMA scientific committees and over 30 working groups now draw on a pool of thousands of European scientific experts from the network to provide scientific expertise in the regulation of pharmaceuticals.

EMA serves a market of over 500 million people living in the EU. The mission of the European Medicines Agency (EMA) is to promote scientific excellence in the evaluation and surveillance of medicines for human and animal health in the European Union (EU).

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Received: 13-Jun-2022, Manuscript No. JP-22-17781; **Editor assigned:** 16-Jun-2022, PreQC No. JP-22-17781 (PQ); **Reviewed:** 30-Jun-2022, QC No. JP-22-17781; **Revised:** 07-Jul-2022, Manuscript No. JP-22-17781 (R); **Published:** 14-Jul-2022, DOI: 10.35248/2329-6887.22.10.382.

Citation: Krzysztof C (2022) Links between Uncertainties Identified by the European Medicines Agency. J Pharmacovigil. 10:382.