The Future of Pharmacovigilance: how to measure the efficacy and effectiveness of some pharmacovigilance processes with the aim of improving them

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Pharmacovigilance have been established with the objective of monitoring the safety of authorised medicinal products and to early detect and manage any change to their risk-benefit ratio. Pharmacovigilance activities applied throughout the product life-cycle include the collection and management of ADR reports, the detection and management of safety signals, proactive planning of risk-minimisation measures and post-authorisation studies. The Regulators have the responsibility to ensure that key pharmacovigilance activities and processes are effective and efficient and continuously improve the pharmacovigilance system to achieve safe and appropriate use of medicinal products and to monitor the outcomes of risk minimisation measures. Measuring impact of pharmacovigilance processes and, then the regulatory actions, represents the “squaring the circle”. In fact, the possibility of measure the pharmacovigilance activities could lead to the improvement of those resulted successful, otherwise to the search for alternative ones to promote best practice and further improve pharmacovigilance. The European Medicines Agency has recently launched an initiative to measure the efficacy and effectiveness of some pharmacovigilance processes with the aim of improving them. In particular, the PRAC strategy is based on four key areas: i) effectiveness of pharmacovigilance processes, ii) effectiveness of product-specific risk minimisation, iii) stakeholder engagement as enabler of effective pharmacovigilance and iv) collaboration on methodologies. This strategy adopted should not leave out of consideration a closer collaboration between all stakeolders but also the lack of harmonization in terms of regulation and guidelines on drug safety at Member State level. In fact, whilst studies to assess the impact of regulatory action are conducted at European level, it is undeniable that national concern and public interest represent the drivers for studies carried out at Member State level. However, study protocols, methods and results from these national initiatives are not enough shared despite nowadays is possible to do it through available tools such as the EU PAS Register. Several guidance and conceptual frameworks have been proposed for the evaluation of effectiveness of risk minimisation measures. An important milestone for pharmacovigilance impact assessment is the model proposed by Prieto et al; In particular his model consists of process indicators and outcome indicators. The former indicators could be used to reflect the degree of prescribers’ acquired clinical knowledge or the actual management of patients. The latter indicators are intended to measure the incidence or severity of adverse drug reactions to be prevented by risk minimisation measures. This model allows the differentiation between the actual implementation of the risk minimisation measure and the attainment of its final objective(s). The model proposed by Prieto et al. forms the basis for a part of the Good Pharmacovigilance Practices Module XVI.7. From Prieto forwards other model have been proposed, such as the hierarchical one of Banerjee et al or the logical one of Kesselheim et al. Actually there is a need to develop novel, robust and more appropriate assessment designs and

methodologies for evaluating the impact and the effectiveness of pharmacovigilance activities, representing, in fact, an evolving field and likely part of the future of pharmacovigilance.