

G7. CURRENT CHALLENGE IN PHARMACOVIGILANCE AT BIO-MANGUINHOS / FIOCRUZ: DETECTION OF DRUGRELATED PROBLEMS IN SOCIAL MEDIA.

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INTRODUCTION Bio-Manguinhos / Fiocruz has been leading original and follow-on biologics joint development and technology transfer processes in order to attend the increasing demand of the Ministry of Health. Alongside this, new challenges have arisen: the establishment of new regulatory standards for pharmacovigilance due to the concern regarding risk-benefit ratio of biologics and the increasing range of social media that can be used to disseminate unreliable information that can jeopardize health programs. Pharmacovigilance is defined as the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

OBJECTIVE To evaluate the current detection methods and new approaches to optimize the efficacy and safety assessment system, envisioning debates and partnerships for the development of optimized pharmacovigilance activities.

METHODOLOGY A situational analysis of pharmacovigilance activities at Bio-Manguinhos / Fiocruz has been developed. Brazilian regulatory agency (Anvisa) and International Conference on Harmonization (ICH) present regulations, partner industries safety data exchange agreements, besides World Health Organization (WHO) guidelines, and Council for International Organizations of Medical Sciences (Cioms) and International Society of Pharmacovigilance (ISoP) recommendations have been accounted. A systematic collection and evaluation of data, aimed at identification of forces that may influence performance and choice of strategies, and

assessment of current and future strengths, weaknesses, opportunities, and threats has been performed and compiled into a matrix.

RESULTS It was found that regulatory authorities, health agencies and scientific organizations are increasingly recognizing the importance of spontaneous reports from persons other than healthcare professionals, and the necessity of social media screening for drug-related-problem monitoring. Voluntary reporting is one of the most versatile pharmacovigilance methods, because, among other advantages, it covers the entire population as well as all drugs throughout their commercial life, being also a process that provides the highest volume of information with relatively lower maintenance cost. The guidelines on good pharmacovigilance practices indicate that marketing authorization holders should regularly screen social media such as websites, Facebook, and Twitter profiles under their responsibility for potential reports of suspected adverse drug reactions, which may characterize a new safety signal, in addition to product complaints, pregnancy and lactation exposures, and unexpected benefits. In order to be in compliance, the Clinical Advisory Unit at Bio-Manguinhos has implemented strategies, including total staff awareness, related organizational units training sessions, pharmacovigilance link creation, and an ever stronger partnership with Communication Advisory, Consumer Care Service and Human Resources teams to support those activities.

CONCLUSION Breaking out of paradigm and investing in innovative pharmacovigilance approaches is essential in face of current regulatory requirements and public opinion about biopharmaceuticals and vaccines. Proactivity in the detection of drug-related problems followed by rapid response certainly can interrupt rumors and raise confidence on public pharmaceutical industry, and also in governmental health programs that have been consolidated over decades.

KEYWORDS drug-related problems, pharmacovigilance, social media.