VI Fórum Internacional sobre Segurança do Paciente
Erros de Medicação

NON-HARMONIZED APPROACH IN MEDICATION ERRORS AND THE POSSIBLE IMPACTS IN THE PHARMACOVIGILANCE SYSTEM: GLOBAL REGULATORY SCENARIO AND BENCHMARKING WITH MULTINATIONAL AND NATIONAL PHARMACEUTICAL COMPANIES

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INTRODUCTION

Errors associated with the use of medicinal products are a major health burden and the cost associated with medication errors has been estimated at US$ 42 billion annually. Monitoring medication errors is important to identify preventative strategies that can be implemented to contribute to reducing the occurrence of errors. Regulatory Agencies (RAs) worldwide require the Marketing Authorization Holders (MAHs) to collect and monitor medication errors involving the products marketed by them. However, the requirements for the management of the distinct types of medication errors by the pharmaceutical industries are not clear, which may lead to a lack of consensus regarding what should be collected and reported to RAs in such scenarios.

OBJECTIVES

Compare the main RAs and International entities' recommendations and the understanding of the Brazilian pharmaceutical industries for the management of medication error cases.

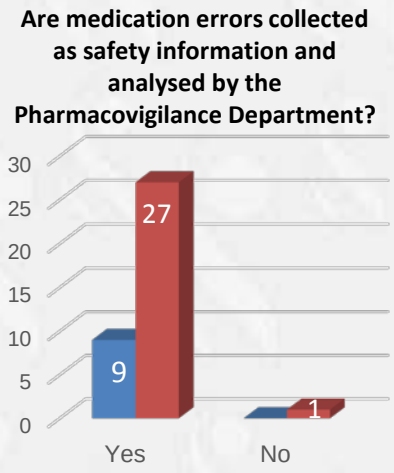
METHODS

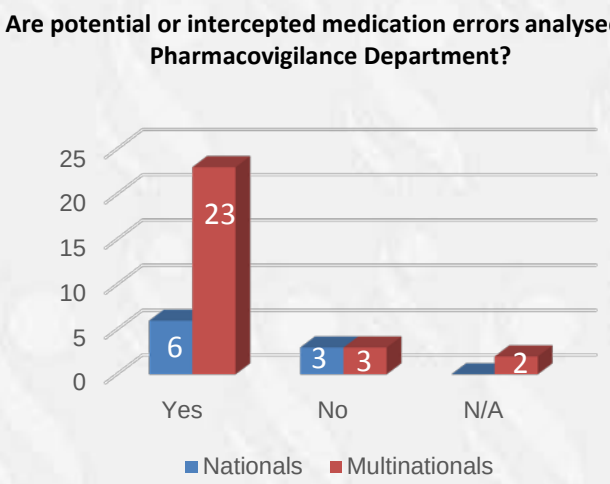
By searching on the following RAs´ websites: Australia, Brazil, Canada, Colombia, EU, Mexico, South Africa and USA, a comparison among the requirements to MAHs related to medication error was established, also considering WHO and ICH's recommendations.

Benchmarking

Questionnaire composed by questions about the criteria for collection and treatment of medication errors by each company.

RESULTS





Benchmarking

	Inquiry only	Intercepted or Potential	Other*
	National + Multinational Companies		
Consumer enquiries about expired product and the possibility to use it.	25	10	2
Consumer enquiries about the use of medication that was wrongly stored.	18	15	4
Use of product with possible quality issue (color alteration, cracked tablets) with no adverse event involved.	0	11	26

* Can include product complaint

Regulation Analysis

- ✓ FDA and COFEPRIS are the only agencies that require individual notification of medication errors by the MAHs.
- ✓ Considering the 8 countries analyzed, in 5 countries we could not find clear regulations regarding the requirements for collection of potential and intercepted medication error.

CONCLUSION

- ✓ There is not a harmonization in the treatment of medication errors among the main Regulatory Agencies.
- ✓ Although most part of the companies based in Brazil collects medication errors, there is a lack of consensus regarding the treatment of potential and intercepted medication error cases.
- ✓ Conservative approaches are being implemented by multinational companies to ensure compliance with, mainly, EMA regulation and therefore, collecting a high number of cases, which are not necessarily relevant from a clinical perspective and might impact the detection of clinically relevant events.
- ✓ More discussions are needed to homogenize understanding about the types of medication and evaluate the impact of overreporting.

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