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Record linkage of pharmacovigilance and registration databases: a study of biological medicines in Brazil

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Introduction

Biologic medicines have revolutionized the treatment of many serious and chronic illnesses and they present important challenges for approval and post-market surveillance of drug safety. Pharmacovigilance is an important strategy for monitoring adverse drug events in the post-market. Drug registration is an essential element of medicine regulation.

Conclusion/Implications

Regulatory actions should be implemented to stimulate adverse events reports of biological products. A single database with registration, post-approval changes and pharmacovigilance data was produced. Data linkage permitted analysis of biological medicines in the post-market and can provide important information to evaluate risk in drug development.

Objectives and Approach

Brazilian Health Regulatory Agency, ANVISA, is responsible for drug registration and surveillance. In this work we describe the process of linkage of databases covering registration, post-approval changes, and pharmacovigilance of biological medicines in Brazil.

2,429,556 registration dossiers included in the comprehensive national drug registration database, DATAVISA, and 93,391 reports of adverse drug events in the pharmacovigilance database, NOTIVISA, were analyzed for completeness and non biologic dossiers were filtered out. Deterministic linkage technique was used to connect DATAVISA and NOTIVISA data.

Results

Of the DATAVISA dossiers, 188,830 were registrations and 2,240,726 records were post-approval changes. After filtering out the non-biologic dossiers, 48,144 post-approval changes dossiers for biologic drugs were obtained. Aggregation of 48,144 post-approval biologic products dossiers resulted in 663 product-manufacturer pairs. For pharmacovigilance data, aggregation produced 5,874 pairs. Registration and post-approval changes merging from aggregated pairs resulted in 577 pairs. Trios with pharmacovigilance data resulted in 147 matches. These 147 pairs respond for 5,468 identified adverse drug events reports. Adverse drug events reports of biological medicines account for around 5,0 % of NOTIVISA.