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REVIEWER'S REPORT

Manuscript No.: **IJAR-53060** Date: 31-07-2025

Title: Application d une approche basee sur les risques pour detecter les medicaments SRMNI de Qualite Inferieure et Falsifies (QIF) au Mali et mesures reglementaires prises

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision .....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality			✓	
Techn. Quality			✓	
Clarity			✓	
Significance			✓	

Reviewer Name: Dr Aamina

Reviewer's Comment for Publication.

Abstract Review:
The abstract effectively introduces the context of increasing concerns around substandard and falsified (QIF) medicines, particularly in the case of multi-source generics. It clearly outlines the objective of the study, focusing on risk-based post-marketing surveillance (RB-PMS) applied in selected regions of Mali. The methodology is concisely described, including the use of the Medicines Risk Assessment Tool (MedRS) developed by USP/PQM+. Key findings are clearly presented with numerical data—89% compliance and 11% non-compliance—along with the geographic and sectoral origin of non-compliant drugs. The abstract concludes with a relevant statement on the importance of drug registration, ongoing quality control, and regulatory vigilance for public health assurance. Overall, the abstract is informative, structured, and aligned with the article's scope.

Introduction Review:
The introduction thoroughly sets the stage for the study. It starts with a relevant discussion on the proliferation of multi-source generics and the heightened risk of QIF drugs. The public health implications are strongly emphasized, particularly within the context of maternal, neonatal, and child health (SRMNI) in Mali. The linkage between elevated mortality rates and limited access to quality medicines is well-articulated. Furthermore, the introduction draws attention to the consequences of QIF medicines, highlighting treatment failure, extended suffering, and potential fatal outcomes. The mention of the national technical working group (GTT-PMS) provides a sense of structured governance and sets up the institutional framework within which the study was conducted. The references to statistical and qualitative impacts strengthen the problem statement.

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General Observations:
The text is well-organized, clear, and presents a strong rationale for the study. The use of data and citations adds credibility, and the topic is both timely and significant in the context of public health and pharmaceutical regulation. The terminology is consistent with academic and regulatory discourse, and the language remains accessible while maintaining scientific rigor.

Overall Assessment:
The article presents a compelling and well-supported analysis of RB-PMS in Mali. Both the abstract and introduction are well-composed, establishing a clear foundation for the study's objectives, methodology, and relevance. The narrative is coherent, evidence-based, and well-contextualized within the broader challenges of healthcare quality and pharmaceutical regulation in West Africa.