

Dear Editor,

We are pleased to submit our manuscript entitled “A mixed-methods framework using fragmentation to establish sampling feasibility of pharmaceuticals” for consideration in Production and Operations Management. This work grew from a collaboration with a chemistry team at the University of Notre Dame that has developed a novel screening tool for substandard and falsified pharmaceuticals. These products constitute a significant barrier to effective treatment of diseases around the world and are most damaging in low- and middle-income countries. The goal of this partnership is to integrate the capacity of a novel screening tool with operations research methods to provide these countries with a toolkit for effective sampling of pharmaceuticals.

Sampling budgets to detect substandard and falsified pharmaceuticals in low- and middle-income countries are often highly limited. In this paper, we propose a mixed-methods framework that accounts for different aspects of a given regulatory environment, as well as different patterns of risk, towards focusing these limited budgets more effectively. We also demonstrate this framework through an ongoing collaboration with the Liberia Medical and Health Products Regulatory Authority (LMHRA). In keeping with the double-blind requirements of POMS, we do not explicitly mention in the manuscript that one of the authors works at the LMHRA.

High-quality pharmaceuticals are crucial for attaining UNSDG #3, ensuring public health and well-being, which is why we feel this paper fits well within the scope of this POMS special issue. Means-limited health ministries require techniques for maximizing the effect gained by leveraging their resources, and our work provides an approach that can be useful as well as be tailored to specific circumstances. Additionally, our use of a mixed-methods framework, coupled with a collaboration among an OR team, a chemistry team, and a national medicines regulatory authority, fits well within the “Multimethod” and “Multidisciplinary” categories of this special issue.

Thank you for your consideration of our research. We look forward to hearing back from you.

Kind Regards,