European Journal of Operational Research 000 (2018) 1–21

Contents lists available at ScienceDirect

European Journal of Operational Research

journal homepage: www.elsevier.com/locate/ejor

Decision Support

The value of entrant manufacturers: A study of competition and risk for donor-funded procurement of essential medicines

Felix Lauton[a,*], Alexander Rothkopf[a,c], Richard Pibernik[a,b]

[a] Chair of Logistics and Quantitative Methods, Julius-Maximilians-University Wuerzburg, Sanderring 2, Wuerzburg 97070, Germany
[b] MIT-Zaragoza International Logistics Program, Zaragoza Logistics Center, Zaragoza, Spain
[c] Center for Transportation and Logistics, The Massachusetts Institute of Technology, USA

ARTICLE INFO

Article history:
Received 5 February 2018
Accepted 7 June 2018
Available online xxx

Keywords:
Humanitarian logistics
Dual sourcing
Competition
Supply risks
Global health

ABSTRACT

Global-health purchasing organizations (POs) want to increase access to essential medicines in low-income countries. One way to purchase more medicines with limited funds is to contract with generics manufacturers, thereby increasing competition and lowering prices. However, many POs fear that these entrants are less reliable than others and increase supply risks: failure to adhere to lead times and supplier defaults may cause disruptions that result in unsuccessful medical treatments. The problem can be remedied or at least reduced if POs have a sound basis for assessing manufacturers. To this end, we develop a mathematical framework that supports decision-makers in an integrated evaluation of an entrant's effect on purchasing costs and supply risks. Our approach accounts for the characteristics of donor-funded global-health markets and the particular tasks and specific challenges of POs in these markets. More specifically, our approach enables a PO to quantify a potential entrant's value depending on important characteristics of the incumbent and the entrant manufacturer. We use data from a project for donor-funded procurement of Depot Medroxyprogesterone Acetate (DMPA) of two large POs. Our results show the feasibility of our approach for POs, manufacturers, and philanthropic investors in the global-health domain, and we explore the trade-off between competition and supply risks and provide insights into how the entrant's value is affected by parameters like production costs, capacity, lead time and default risk, and in-country registration.

1. Motivation

Researchers and practitioners have discussed extensively the pros and cons of single-sourcing and multiple-sourcing with respect to such issues as risk exposure, competition, production costs and overall purchasing costs. However, most of the academic research has focused on individual aspects of the single-versus-multiple-sourcing problem. For instance, researchers have addressed managing a company's risk exposure (e.g. Tomlin, 2006; Tomlin & Wang, 2005) and the impact of competition on prices and purchasing costs (e.g. Gong, Li, & McAfee, 2012; Perry & Sákovics, 2003). Addressing these individual parts of the problem has led to rich and complicated formal analyses that have often yielded very interesting results from an academic viewpoint, but decision-makers in practice usually require more comprehensive answers: They want to know how many manufacturers they should contract, how they should split the procurement volume among these manufacturers, and what procurement mechanism they should employ in order to strike an optimal balance between purchasing costs and supply risks.

One domain in which these issues are particularly pertinent is the donor-funded global-health market, where a significant portion of the procurement of essential medicines (e.g., medicines to treat malaria, HIV/AIDS, tuberculosis; reproductive health products; and a variety of vital vaccines) is carried out by global purchasing organizations (POs), such as the United Nations Children's Emergency Fund (UNICEF) and the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria. These POs consolidate the demands of low-income countries, negotiate favorable terms with pharmaceutical manufacturers, and take an active role in ensuring that the medicines they purchase reach the population. With few exceptions, these POs are allowed to procure only from manufacturers that undergo for each drug a strict quality assurance process known as "WHO-Prequalification" (WHO, 2016) and/or that are accredited by large stringent regulatory authorities like the US Food and Drug Admin-

* Corresponding author.
E-mail addresses: felix.lauton@uni-wuerzburg.de (F. Lauton), rothkopf@mit.edu (A. Rothkopf), richard.pibernik@uni-wuerzburg.de (R. Pibernik).

https://doi.org/10.1016/j.ejor.2018.06.027
0377-2217/© 2018 Published by Elsevier B.V.

istration (USFDA). As a result, only one or two manufacturers are pre-qualified, and these are usually branded manufacturers that do not provide generics.[1] In addition, manufacturers must register their products in the low-income countries. The in-country registration and the WHO-prequalification process can be complex and may take more than a year, depending on the manufacturer's experience.

Clearly, such monopoly or duopoly situations diminish the POs' bargaining power, so they are interested in increasing the number of manufacturers that are pre-qualified for a particular drug. However, obtaining pre-qualification is difficult, time-consuming, and costly. When manufacturers apply for pre-qualification, they do not know how much volume they will be awarded, if any, or whether the qualification process and any investment in capacity will pay off. What they do know is that the (monopoly) incumbent has a strong position and is likely to take measures to defend its position—before, during, and after the new manufacturer's entry.

The POs and other stakeholders in the global-health domain can incent potential entrants to pursue pre-qualification and to invest in manufacturing capacity by, for example, providing financial or management support and/or promising to procure certain volumes from the entrant. However, whether a PO should undertake such measures raises the question that lies at the heart of our study: How much value does a new entrant provide to the PO? Answering this question is not trivial: First of all, the PO needs to gauge how the entry of a new manufacturer will impact the purchasing prices. Clearly, prices should decline with increased competitive pressure, however, the ability to lower prices depends on the differential in costs and capacities between the incumbent and the entrant(s).

Despite the potential benefits of additional entrants, POs are often hesitant to employ generics manufacturers, even if they are already pre-qualified or will obtain it in the future. This reluctance is due primarily to supply risks, which POs often perceive as being higher than the supply risks of the incumbent (branded) manufacturers that have an established track-record for delivery performance. The perception of a greater supply risk for new generics manufacturers has been fueled by a number of incidents in which manufacturers caused supply disruptions because they did not meet lead-time expectations, had temporary production/supply outages, lost their pre-qualification, or defaulted entirely.[2]

The inability to quantify the effects of a new entrant on purchasing costs, the higher (perceived) risk, and other hard and soft factors (e.g., higher transaction costs, higher personal effort, a long-standing relationship with the incumbent) often lead POs to stay with the incumbent manufacturer rather than incenting potential entrants to seek pre-qualification and entering into purchasing contracts with them. Therefore, potential entrants, especially generics manufacturers, are even less incented to make the investment required to enter the donor-funded market.

This problem can be remedied (or at least reduced) only if POs have a sound basis for assessing a new manufacturer's value—that is, only if they can evaluate and trade-off the effects of competition on purchasing costs and the effects in terms of supply risks. The objective of the research we present in this paper is to provide POs in the global-health domain with rigorous decision support for such assessments. We propose an approach that supports an integrated evaluation of an entrant's effect on purchasing costs and supply risks depending on the volume split a PO chooses between its suppliers. Our approach accounts for the characteristics of donor-funded global-health markets and the particular tasks and specific challenges of POs in these markets. More specifically, our approach enables a PO to quantify a potential entrant's value depending on important characteristics of the incumbent and the entrant manufacturer. We use a case study to demonstrate our approach's applicability and to highlight how it can provide effective decision support for a PO.

Our research contributes to the comparatively new literature stream that seeks to evaluate competition benefits *and* supply risks jointly. We present an integrated approach to evaluating competition benefits and supply risks that depends on how the PO splits the volume between an incumbent and an entrant manufacturer. Our approach enables us to determine the optimal volume split and to quantify the value of a potential new entrant based on that split. The proposed approach is also novel from a methodological point of view: We extend the concept of bilateral bargaining to account for volume splitting. This allows for an adequate representation of the negotiations between the PO, the incumbent, and the entrant, and enables us to study how alternative volume splits affect competition.

The remainder of our paper is organized as follows. Section 2 introduces the example case that motivates our research and develops a set of detailed research questions to guide our analyses. After a brief literature review in Section 3, Section 4 provides a formal characterization of the problem the PO faces. More specifically, Section 4 presents two related sub-models that provide a realistic representation of the interactions among the PO, the manufacturers (an incumbent and a new generics manufacturer), and the recipient countries. To show the applicability of our approach and to derive meaningful results for the PO, we implement our mathematical models in a simulation tool and carry out extensive analyses based on real-world data from several sources. The simulation model, our analyses, and insights and recommendations for the POs are described in Section 5.

2. Practical setting and research questions

2.1. The DMPA case

We use a case example to develop our approach and to highlight its applicability. In 2015 we carried out a study to support decision-making at two POs, the procurement divisions of the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID), both of which procure the majority of donor-funded Depot Medroxyprogesterone Acetate (DMPA), an injectable contraceptive, for low-income countries. At the time of our study, only one manufacturer, Pfizer, held the necessary pre-qualification for providing the drug, although it seemed likely that a generics manufacturer would obtain pre-qualification for DMPA in the near future. To address the problems associated with an entrant manufacturer and to support the POs in their procurement decisions regarding DMPA, we analyzed the competition and the risk effects associated with the new entrant and quantified its value for the PO dependent on parameters that were not perfectly known to the PO at the time (e.g., the entrant's capacity, the cost differential between incumbent and entrant, the entrant's lead time).

POs are intermediaries that consolidate demand from multiple low-income countries and negotiate prices and delivery terms with the manufacturer(s) on behalf of the recipient countries. For example, UNFPA consolidates the demand from the sixty-nine countries that the global-health community deemed to be focus countries for reproductive health efforts in 2012 (FP2020, 2016). POs also take an active role in coordinating supply from the manufacturer(s)

[1] For example, Pfizer is the only pre-qualified manufacturer for the injectable contraceptive Depot Medroxyprogesterone Acetate (DMPA), a key reproductive health product; only Bayer and Merck currently hold pre-qualifications for contraceptive implants, another key reproductive health product; and only Alkem Laboratories and Rodael Laboratories have pre-qualifications for Zinc Sulfate, which is important for treating diarrhea (WHO, 2016).

[2] For example, WHO suspended pre-qualification for manufacturers of yellow fever vaccine (UNICEF, 2013) and a manufacturer of HIV medicines (FM't Hoen, Hogerzeil, Quick, & Sillo, 2014).

Please cite this article as: F. Lauton et al., The value of entrant manufacturers: A study of competition and risk for donor-funded procurement of essential medicines, European Journal of Operational Research (2018), https://doi.org/10.1016/j.ejor.2018.06.027