Planning operations before market launch for balancing time-to-market and risks in pharmaceutical supply chains

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Shorter product life cycles and the resulting increase in new product introductions boost the importance of product launch operations. In the pharmaceutical sector, product launch operations are of particular importance, as companies seek to reduce time-to-market to better exploit patent protection. Large volumes of product need to be ready to fill the downstream supply chain immediately at market launch. Building up the required inventory is, however, connected to several risks. In addition to the risk associated with the lack of demand information for a new product, there are several risks unique to the pharmaceutical sector. After approval by central authorities such as the FDA or EMA, a new drug still needs to receive market authorization, which is in most cases granted by some local authorities – in Europe, for example, by more than 30 national and regional bodies. The duration of these different market authorization processes as well as their outcomes (e.g. price and reimbursement levels, requirements of label or leaflet changes) are highly uncertain. We develop a two-stage stochastic model to support market launch preparation decisions. It trades off the costs of accepting these risks, for example by risk packaging before authorization, against the lost revenue caused by risk-averse operations. The model is applied to a case based on an empirical study. Our approach results in significant savings compared to current practices. We hereby provide an example of how quantitative methodology can provide valuable decision support for product launch operations, even when complex regulatory affairs need to be considered.

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