Supply Network Planning for New Product Market Entry in the Pharmaceutical Industry

It is well known, that the pharmaceutical industry is struggling with increasing cost and length of R&D projects. Earnings of a drug drop drastically after patent expiration. Thus, the industry spends much effort on reducing Time-to-Market. In the literature, no attention is given to supply chain planning before and during the market entry of the drug after the drug has been approved. Production of the active pharmaceutical ingredient [API] is characterized by long change-over times due to cleaning requirements. Production planning is long term, multiple batches of each drug are produced in succession and each drug is only produced few times annually. Assuming fixed intermediate availability of API, supply network planning consists of finding inventory levels and production volumes for downstream stages to cope with the highly fluctuating demand of new markets. Unique for the pharmaceutical industry, reimbursement negotiations have to be carried out before a drug can be marketed. These negotiations both necessitate time phasing market entries and introduce a series of uncertainties e.g. varying allowed price and awarded subsidy. Also if the label is not approved for marketing, all packaged products have to be scrapped. We have developed an MILP supply network planning model, which sets time phased market entries and finds inventory levels and production volumes to balance fluctuating demand with fixed periodic production of the API. Our model is recourse-based and considers demand uncertainty and the risk of a forced label change and includes solution robustness. While considering limited shelf life of the drug, the supply of packaging material and outsourcing, the objective of our model is to reduce supply chain cost including lost peak sales from delayed market entry.