

5. Abstract

Title: Legal aspects of a parallel trade in drugs within the EU

Key words: single market, parallel trade, price regulation, pharmaceuticals

Parallel trade is one of the most distinctive benefits of the European single market. In a simplified way, parallel trade is legal importing of drug from one country where it is legally marketed into a second country where the marketing authorization holder also markets that product, but without the consent of the marketing authorization holder. Price regulation of medical products makes parallel trade of drugs questionable. Final price for customer is not result of an independent decision of pharmaceutical company but it is given by relevant authority often regarding the spending power of citizens. Wholesalers are taking advantage of these price differences when they are buying cheap drugs in low-price countries and selling them with profit in countries where drug price are higher. In theory this practice should deliver significant saving for patient and national healthcare insurance system in destination countries due to lower price of parallel traded drugs. However many studies show minimum impact on drug price in these countries since wholesalers retain great part of the financial benefits. On the other hand, negatives of parallel trade are evident. Drug shortage in low-price markets is characteristic side effect. Less evident issues is represented by significant financial loss for pharmaceutical companies which carry major part of new drugs R&D cost.

This thesis offers overview of legal aspects of a parallel trade in drugs within the European union. First part of thesis includes detailed definition of term parallel trade and introduction into relevant legislation. The second and third parts describe ways how pharmaceutical companies and member states are facing up to problems caused by parallel trade.