Background and importance

The aim of the Falsified Medicines Directive 2011/62/EU (FMD) is to prevent the entry of illegitimate medicines into the legal supply chain. Despite its proposed benefits, the in-depth evaluation of cost implications for hospital pharmacies is still lacking. It has been estimated by the European Commission that the annualized cost for a hospital pharmacy will be 750 €/institution.

Aim and objectives

Our study evaluates current practice of serialization and the financial impact of the FMD in a representative sample of Hungarian hospitals.

Material and methods

Based on literature review and interviews with hospital pharmacy experts, a 41 item questionnaire was developed to evaluate the implementation process leading up to February 2019, and the stabilization period that followed. Questions regarding institutional data, human resource requirements, infrastructural and IT developments and authentication procedures were sent out to all (n=96) Hungarian hospital pharmacies in September 2019. Pilot Data collection started from February 2019.

Results

High response rate (n=43, 44,8%) permits representative data evaluation of Hungarian hospitals. Respondents cover 49,2% of all active beds/acute care and 52.9% of chronic care/beds in Hungarian hospital. By the initial launch date of FMD, the average increase in pharmacist workload was 0,92 (±1,98) hours/day, and it is estimated to increase further by 1,13 (±1,65), equaling 0,25 pharmacist full-time-equivalent (FTE)/institution. Additionally, FMD seemed to increase technician workload significantly compared to pharmacists (p<0,001), as by February 2,25 (±1,42) hours, and in the long term there was a further 4,01 (±3,38) daily working hour increase was reported (equating approx. 0,75 technician FTE/institution).

Average non-human resource (e.g. infrastructural, IT, etc.) costs related to the implementation of the Directive in February 2019 was 1868 EUR/institution with a high variation (±3331 EUR) due to inter-institutional differences, however significantly lower costs are expected in the long term in the stabilization phase (42±2785 EUR).

FMD has affected the hospital supply chain by numerous means, as 76,7% of the respondents faced drug shortages of these products, 58,1% have reported increased drug costs of serialized medications, and 53,5% noticed increase in packaging size affecting storage capacities.

Conclusion and relevance

Our results illustrate that the FMD has notable short and long term impact on hospital pharmacies. Even the infrastructural and IT development costs for the implementation and stabilization period of FMD for Hungarian hospitals exceeds more than two times the previous EU estimations. The aim of the authors is to adapt this methodology to other EU countries, and identify good practices in serialization at an international level.