HOW MUCH DOES FALSIFIED MEDICINES DIRECTIVE ACTUALLY COSTS? *DETAILED COST EVALUATION OF SERIALISATION IN A REPRESENTATIVE SAMPLE OF HUNGARIAN HOSPITAL PHARMACIES*

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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 (±0,98) 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 a further 4,01 (±3,88) daily working hour increase was reported (equaling 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 (421±785 EUR).

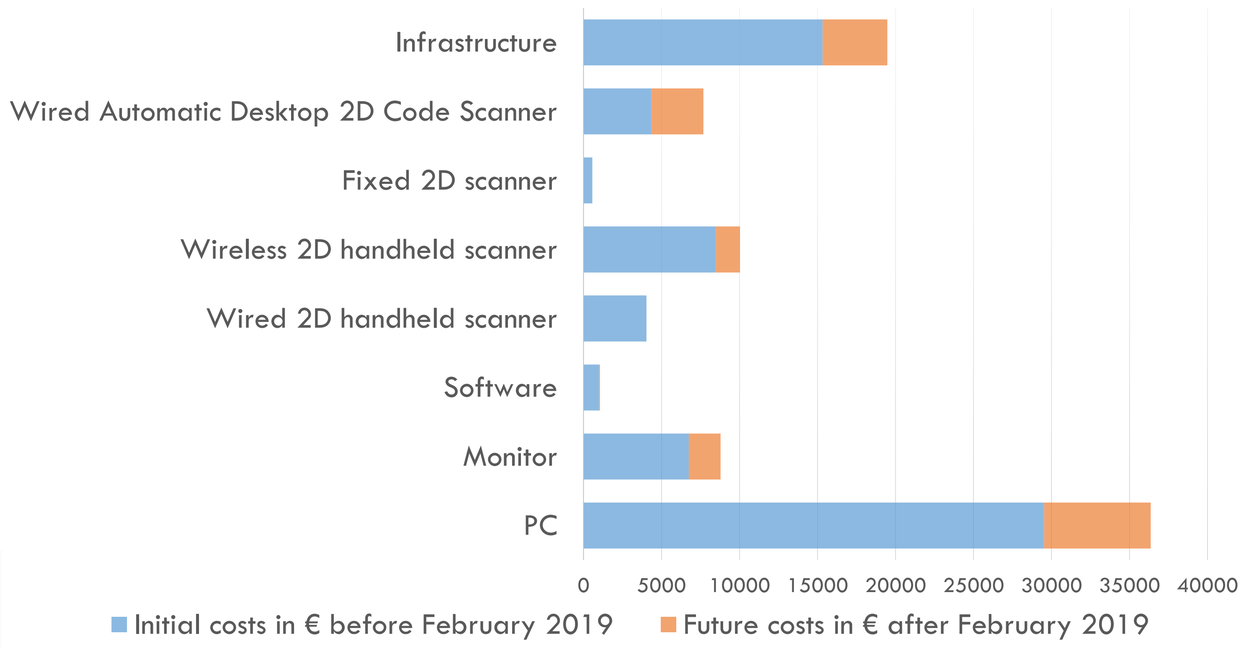
FMD has affected the hospital supply-chain by numerous means, as 76,7% of the respondents faced drug shortages of these products, 58,1% have reported suspected increase in drug costs of serialized medications, and 53,5% noticed increase in packaging size affecting storage capacities.

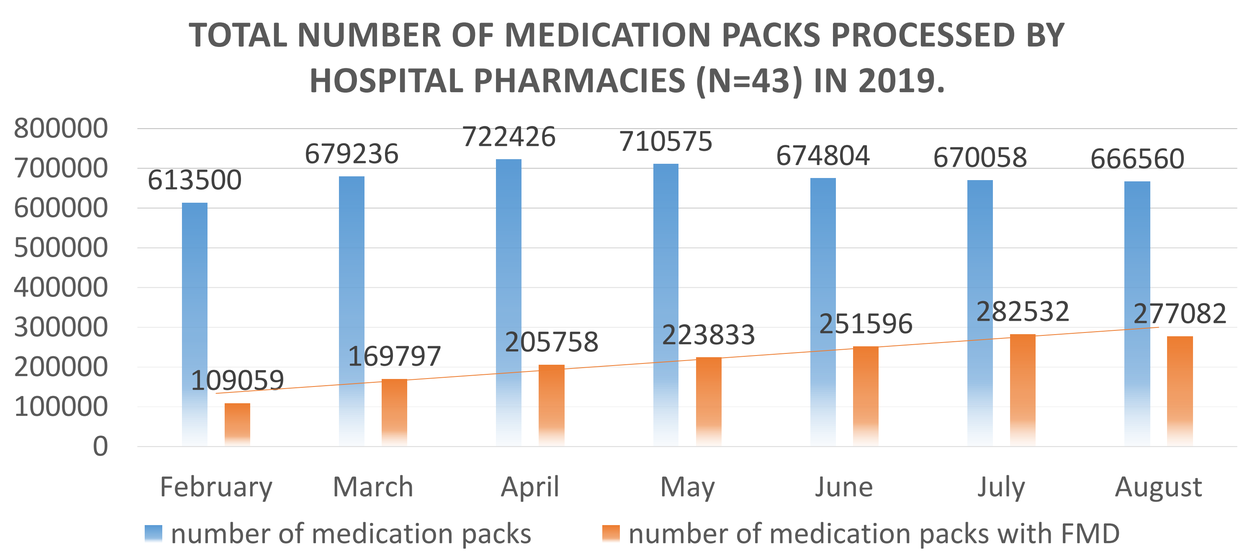
Conclusion and relevance

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.

Hospital pharmacy characteristics (n=43)	
Number of hospital pharmacy units receiving medications from wholesalers	
1	38
2 or more	5
Operation of a community (retail) pharmacy unit	
Yes	30
No	13
Number of inpatient hospital beds	
Acute care (total)	20751
mean acute beds/institution (±SD)	482,6 (± 390,2)
Chronic care (total)	10983
mean chronic beds/institution (±SD)	255,4 (± 175,1)
Institution size (n)	
Small (less than 500 beds)	19
Medium (500 – 1000 beds)	11
Large (more than 1000 beds)	13
Number of separate institutions, health facilities supplied by respondents	
None	22
1	13
2 or more	8
Serialization technique (authentication and decommissioning)	
One step	32
Separate step	11

			1-500 beds			501-1000 beds			above 1000 beds		
			N	Mean	Std. Deviation	N	Mean	Std. Deviation	N	Mean	Std. Deviation
Workload increase (hours/day)	pharmacist	initial	19	0,86	1,25	11	0,96	0,71	13	0,96	0,78
		future estimte	19	0,74	1,78	10	1,30	1,23	13	1,58	1,73
	technician	initial	19	2,03	1,54	11	1,54	0,56	13	3,19	1,32
		future estimte	19	3,05	3,47	10	2,75	1,32	13	6,38	4,84
Non-human resource (infrastructural & IT) costs in EUR		initial	18	657	646	11	1414	984	13	3972	5466
		future estimte	17	265	589	10	1006	1156	13	187	435
			N	Frequency	%		Frequency	%		Frequency	%
One step verification and decommissioning			19	16	84,2	11	7	63,6	13	9	69,2
Faced drug shortages			19	14	73,4	11	9	81,8	13	10	76,9
Suspected increase in drug costs			19	9	47,4	11	5	45,5	13	4	30,8





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