manufacturing problems (66.7%), tendering processes (54.8%) and raw material supply problems (52.4%). Serialisation was also mentioned (16%) as a cause of drug shortages.

Conclusion and relevance This is the first time a drug shortage survey focusing on Hungary has been completed. The data and tendencies collected were mainly in accordance with results of previous surveys and global tendencies. However, a new finding is that drugs belonging to ATC group B were affected the most by supply disruptions in Hungary. In addition, this is the first time that serialisation was linked with drug shortages in a survey.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-022 DRUG SHORTAGES AND DRUG UNAVAILABILITY: ANALYSIS FROM AN ITALIAN HOSPITAL

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Background and importance Medication shortages and unavailability have become a growing worldwide issue because of their possible clinical impact: reasons can be related to parallel trading (drug unavailability) or lack of production (drug shortages). When they occur, identifying a similar drug may be required or the drug is imported from abroad.

Aim and objectives The aim of the study was to perform an analysis of drug shortages (DS) and drug unavailability (DU) occurring at the centre from January 2018 to June 2019.

Material and methods The analysis included every DS and DU for every drug included in the formulary from January 2018 to June 2019. Any drug request received by the pharmacy during this time was analysed to determine DU and DS, and the drugs involved. Classification of DU or DS was performed through consultation on the DS list published by the Italian Medicines Agency. The analysis was performed for three time points: first semester 2018 (S1), second semester 2018 (S2) and first semester 2019 (S3). Also, an analysis of the medication group involved over time was performed.

Results The analysis detected DU for 19 drugs included in the formulary: S1: (2: intravenous ampicillin 1 g, cefazidime 1 g), S2: (5: intravenous midazolam 5 mg, oxacillin 1 g, iron glucosenate 62.5 mg, methylprednisolone 40 mg, glutathione 600 mg), S3: (12: intravenous piperacillin/tazobactam 2.25 g and 4.5 g, lysine acetylsalicylate 500 mg, hydrocortisone 100 mg, suxamethonium 5 mg, cefazidime 1 g and 2 g, cefepime 2 g, glutathione 600 mg, methylprednisolone 40 mg, heparin 5000 units, atracurium 50 mg). Ten cases of DS requiring importation were found: S1: (4: mupirocin 2% nasal ointment, intravenous chlorphenamine 100 mg, alprostadil 20 µg, etilefrine 10 mg), S2: (3: intravenous diazepam 10 mg, lorazepam 4 mg, fructose 5 g), S3: (4: oral labelol 5 mg, danazol 200 mg, sodium nitroprusside 50 mg, intravenous fructose 5 g). Medications groups involved in DU and DS were: antibiotics (31%), non-steroidal anti-inflammatory drugs (20.7%), benzo-diazepine (10.4%), anti hypertensive (10.4%), dietetics (10.4%), anaesthetics (6.9%), urological drugs (3.4%), antihistamines (3.4%) and adrenergic drugs (3.4%). The rate of DS did not change over time, while DU increased from S1 to S2 (+150%) and from S2 to S3 (+150%).

Conclusion and relevance While the number of DS requiring drug importation remained almost constant, DU strongly increased over time, leading clinicians to identify similar treatments. The analysis did not show any prevailing medication group over time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-023 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 (FMD 2011/62/EU) is to prevent the entry of illegitimate medicines into the legal supply chain. Despite its proposed benefits, the indepth evaluation of cost implications for pharmaceuticals is still lacking.

Aim and objectives Our study evaluated the current practice of serialisation 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 stabilisation 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.

Results A high response rate (n=43, 44.8%) allowed representative data evaluation of Hungarian hospitals. By the initial launch date of FMD, the average increase in pharmacist workload was 0.92 (±0.98) hours/day, and it was estimated to increase further by 1.13 (±1.65), equalling 0.25 pharmacist full time equivalents (FTE)/institution. Additionally, FMD seemed to increase technician workload significantly compared with 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 (equalling approximately 0.75 technician FTE/institution). Average non-human resource (eg, infrastructural, IT, etc) costs related to the implementation of the directive in February 2019 were 1868C/institution with a high variation (±3331C) due to inter-institutional differences but significantly lower costs are expected in the long term in the stabilisation phase (421±785C). FMD has affected the hospital supply chain in numerous ways, as 76.7% of respondents faced drug shortages, 58.1% reported suspected increases in drug costs of serialised medications and 53.5% noticed an increase in packaging size affecting storage capacities.

Conclusion and relevance Our results illustrated that the FMD had notable short and long term impact on hospital pharmacies. Our aim is to adapt this methodology to other EU countries and identify good practices in serialisation at an international level.
REFERENCES AND/OR ACKNOWLEDGEMENTS

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SHORTAGES OF MEDICINES IN HOSPITAL: RESULTS OF A SURVEY ON THE PERCEPTION OF HEALTH WORKERS IN THE WARDS VSV REAL WORLD

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Background and importance Medicine shortages in Italy are an increasing phenomenon with significant impact on clinical activity.

Aim and objectives The aim of the study was to analyse the phenomenon, creating monitoring methods that can support the health workers (HW) involved in the problem.

Material and methods The hospital pharmacy (HP) developed a survey for HW, aimed at determining which types of drugs are most subject to unavailability, incidence and average duration of the phenomenon, approach used in managing any criticality and the impact on clinical practice.

Results A total of 59 HW from 14 different departments interviewed. The classes of drugs reported most were: antibiotics (38.0%), corticosteroids (10.6%), gastroprotectors (8.8%), antihypertensives (7.1%), benzodiazepines and psychostimulants (5.2%), nutritional agents (4.4%), antihistamines (4.4%), blood products (3.5%), biologicals (2.6%) and others (14.8%). In 88% of the shortages, at least one medicine in the reference period (12 months) was reported, with an average duration of 2–8 weeks. Thirty-four per cent of respondents stated that the shortage of drugs had a negative impact—namely, the effect was perceived as very relevant in 5.9% of reporter cases since HW had to wait for the Italian Medicines Agency Nulla Osta for parallel importation; and relevant in 41.2% of cases, as HW had to wait for the HP to obtain supplies. In the remaining 52.9%, the impact was judged to be minor due to the presence of alternative therapeutic solutions. Specifically, in 11.4% of cases, a generic medicine was prescribed, based on the same active substance (AS) but with a different pharmaceutical form (8.6%) or different dosage (14.3%), and in the remaining 65.7% a medicine contained a different AS. The 17% of HW stated that the deficiency had never been solved, as in the case of oxacillin 1 g vials, ceftazidime 2 g vials, linsine acetylsalicylate 500 mg vials and danazol 200 mg tablets.

Conclusion and relevance The data collected confirm that the phenomenon of shortages is growing, highlighting the classes of medicines that are to be monitored to prevent the phenomenon. The tool used may be useful for improvement of the activity and efficiency of HP, with the aim of reducing the negative effects on daily clinical activity through constant comparisons between HW and HP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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APPLICATION OF HAZARD VULNERABILITY ANALYSIS TO EVALUATE THE RISK LEVEL OF MEDICINE SHORTAGES

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Background and importance Drug shortages have become a worldwide phenomenon which has repercussions on patient care and on the hospital’s budget.

Aim and objectives The aim of our study was to assess the risk of shortages of drugs included in our hospital therapeutic formulary (HTF), for which there is shortage reporting, using a hazard vulnerability analysis (HVA).

Material and methods We performed an HVA on 43 drugs in our HTF, which were also included in the Italian Medicines Agency list of shortages. The HVA used to assign the risk of shortage (ROS) included three macro areas: probability that the shortages will occur based on shortages in the past 2 years; magnitude factors which increase the risk of shortages; and mitigation factors which reduce it. Probability was assigned a score from 0 to 2 based on previous shortages.

Magnitude factors were relevance of active substance; budget impact; and percentage of patients treated. Mitigation factors were: therapeutic alternative; stock availability; and import of drug. For each of these items a score from 0 to 3 was assigned. For magnitude factors, a higher score was assigned for increasing severity values. In contrast, for mitigation factors, a higher score was assigned in relation to mitigation reduction. The value of the risk was calculated multiplying the percentage of probability (P) and the percentage of severity (S). According to the score obtained, three classes of ROS were assigned: low (<30%); medium (30–60%); and high (>60%).

Results No drug was found to be at high risk of shortage (>60%), 32/43 (74.4%) were at low risk of shortage and 11/43 (25.6%) were at medium risk of shortage. The latter had previously been lacking; 6/11 had the same active ingredient as a therapeutic alternative, 3/11 had a different active ingredient as an alternative while 2/11 had no alternative.

Conclusion and relevance The HVA is an important method to assess the ROS and implement targeted strategies for drugs at risk of shortages. Knowledge of the risk level facilitates the timeliness of the interventions to resolve the shortages themselves.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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MANAGEMENT OF DRUG SHORTAGES

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Background and importance Drug shortages (DS) are a current global health issue facing pharmacists, prescribers and patients. To deal with DS, pharmacists are forced to resort to different