

**Background and importance** The complexity in the design and execution of clinical trials has created the need to coordinate a multidisciplinary team in which the pharmacist has a fundamental role to avoid medication errors (ME).

ME are especially important in clinical trials since any minimal deviation in the protocol can lead to the patient leaving the study.

**Aim and objectives** To analyse the medication errors detected in the clinical trials area of the Clinical Research Onco-Hematologic Pharmacy Unit, in order to identify the points of greatest risk and establish improvement measures.

**Material and methods** A prospective analysis of medication errors detected during 6 months (January 2021–June 2021) was conducted by pharmacists in the Clinical Research Onco-Hematologic Pharmacy Unit in the course of their activity. At the same time, the errors detected during the validation of the medical prescriptions and during the quality control of the intravenous preparations were analysed.

**Results** A total of 250 errors were recorded. Most of the errors detected (n=135; 54%) originated in the prescription process, of which the most frequent were: error in the patient's weight (31.11%), the prescription of an incorrect dose (26.67%), prescribing the wrong chemotherapy regimen (17.78%), errors in the confirmation of treatment (8.15%), and others (16.29%). In 8 (5.93%) cases, the error reached the patient. None of these caused serious consequences.

Regarding the preparation process, 115 (46%) errors were detected. 63.47% were due to errors in the conservation specifications: 57.39% storage temperature specifications and 6.08% related to photoprotection. 21.90% confusions that required a repeat of the preparation and 20% that referred to infusion systems.

**Conclusion and relevance** Most of the ME that occurred in the Clinical Clinical Research Onco-Hematologic Pharmacy Unit are intercepted before they reach the patient. Most of them were generated in the prescription process, mainly due to an error in the patient's weight.

The information obtained in this analysis reinforces the role of the clinical pharmacist in avoiding errors and improving measures to increase patients' safety.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of interest** No conflict of interest

### 5PSQ-125 THE IDENTIFICATION OF HEALTH CONSEQUENCES ASSOCIATED WITH COUNTERFEIT MEDICINE AND ILLEGAL HEALTH PRODUCT APPLICATION USING PHARMACOVIGILANCE DATA

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**Background and importance** Information on the health damage caused by counterfeit medicines and healthcare products is not, or is only rarely found, in the scientific literature. As a result it is difficult to determine or describe in clinical practice the extent and probability of drug-related problems originating from these products and how to identify these harms in a hospital setting.

**Aim and objectives** Our aim was to assess the active pharmaceutical ingredients affected, the extent and characteristics of

health consequences related to counterfeit medications based on the accessible product alerts and pharmacovigilance data.

**Material and methods** In addition to doing a literature search, we reviewed the World Health Organization (WHO) Medical Products Alert publications in the last 20 years and collected adverse drug reactions indicating a counterfeit medicine in the WHO VigiAccess database. Furthermore, we analysed the counterfeit medicine-related adverse drug reactions in the US Food and Drug Administration (FDA) Adverse Events Reporting System (FAERS) database.

**Results** The top 12 most commonly involved active substances internationally were alprazolam, amoxicillin/clavulanic acid, bevacizumab, diazepam, phenobarbital, flunitrazepam, glibenclamide, heparin, insulin, levonorgestrel, sildenafil and tadalafil. Between 2003 and 2020 in the FAERS database, we identified 3868 falsified drug-related adverse drug reactions, and in the last 5 years an average of 300–500 cases, which represents 0.018% of all reported adverse drug reactions. Based on the FAERS cases we have identified less predictable adverse drug reactions as well, with PDE-5 inhibitors causing vision loss and eye bleeding, and alprazolam causing foaming mouth and suicide attempt.

**Conclusion and relevance** Our study showed that pharmacovigilance and toxicovigilance data are suitable for the identification and detection of health damage caused by counterfeit drugs. With the national adaptation and the development of a specific prospective data collection methodology in the clinical setting, it may also be possible to identify cases in Hungary, which will be a great step towards the prevention of patients' health damage and death related to these products. We believe that clinical pharmacists should play a more definite role in adverse drug reaction identification and toxicovigilance.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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### 5PSQ-127 THE IMPACT OF COMEDICATION ON POTENTIAL LIVER TOXICITY OF REMDESIVIR: A DESCRIPTIVE, RETROSPECTIVE ANALYSIS OF HOSPITALISED COVID-19 PATIENTS

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**Background and importance** Although the safety of remdesivir has been shown previously, liver toxicity is an ongoing concern. Additionally, case reports were published suggesting a possible interaction between remdesivir and Cyp3A4 and/or P-glycoprotein (P-gp) inhibitors, resulting in liver toxicity. COVID-19 infection itself may cause liver toxicity through various mechanisms.

**Aim and objectives** The aim of this analysis was to evaluate the impact of concomitant medication of COVID-19 patients on liver toxicity of remdesivir.

**Material and methods** This descriptive, retrospective analysis included hospitalised COVID-19 patients treated in regular wards from February to April 2021. Remdesivir was prescribed according to the hospital's standard operating procedure (SOP). Treatment with remdesivir was only initiated in patients with evidence of COVID-19 pneumonia and symptom onset to hospital admission  $\leq 7$  days. Patients with pneumonia and high risk of bacterial infection received ceftriaxone as

part of the SOPs. Data were obtained from medical charts and included demographic characteristics, concomitant medication and laboratory results of liver function (at admission and after about 5 and 10 days of hospitalisation).

**Results** 30 patients received remdesivir during the observation period, and in addition 11 patients without remdesivir were included as controls. Median time from symptom onset to hospitalisation was 4 days for the remdesivir group and 10 days for patients not treated with remdesivir. Remdesivir was prescribed in 17/30 patients (56%) without any other pharmacologically relevant medication. 13 patients (43%) received remdesivir together with ceftriaxone. There was no evidence of liver dysfunction, defined as alanine transaminase (ALT) values above 2.5 times the upper limit of normal, in patients with remdesivir with or without concomitant ceftriaxone. 3 patients (50% total) who received ceftriaxone without remdesivir had evidence of liver enzyme dysfunction. Only 1 patient received a P-gp inhibitor (carvedilol, 25 mg) together with remdesivir; however, no effect on ALT levels was observed.

**Conclusion and relevance** In this small sample retrospective study there was no evidence of clinically relevant liver toxicity with remdesivir, with or without other drugs that would impact liver enzyme function, such as ceftriaxone. Interactions with potent Cyp3A4 or P-gp inhibitors appear to be rare in a real-life clinical environment.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

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#### 5PSQ-128 CLINICAL INTERVENTIONS IN THE AREA OF INPATIENT PRESCRIPTIONS PERFORMED BY A HOSPITAL PHARMACY RESIDENT

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**Background and importance** Pharmaceutical validation of inpatient treatments is a fundamental activity in the clinical practice of the hospital pharmacist. Thanks to this, many prescription errors are detected, promoting patient safety.

**Aim and objectives** To describe the interventions performed by a hospital pharmacy resident in the area of pharmaceutical validation, supervised by consultant pharmacists, and to evaluate their degree of acceptance.

**Material and methods** Prospective interventional study conducted during September 2021. Adult inpatients, whose hospital treatment was reviewed, were included. Demographic (sex and age), clinical (clinical judgement (CJ) and inpatient clinical service) and pharmacotherapeutic (number of chronic medicines and polymedication ( $\geq 6$  drugs)) variables were collected. Interventions were reported to the clinician via electronic prescribing software. They were classified as: Activity (reconciliation on admission/information to the clinician), Adequacy (detection of prescribing error/therapy reconciliation error), Change (therapeutic exchange), Initiation (usual treatment not prescribed/need for additional treatment), Modification Dosage Form (DF) or Posology, Suspension (duplication/unnecessary medication/allergy). Patient lists and data were collected through medical records and electronic prescribing software, and processed using Excel 2020.

**Results** Interventions were performed in 56 patients. 63.2% male; median age 73 years (IQR 61–80). The most frequent CJ were: heart failure (10.7%), COVID-19 (7.1%), liver dysfunction (7.1%). Services with most interventions: Internal Medicine (25.8%), General/Vascular Surgery (19.4%), Digestive (11.3%). Median number of chronic medicines: 8 (IQR 5–12). Polymedication in 71.4%. 62 interventions were performed (12.9% were 'not evaluable', reasons: discharge/death). Of the evaluable interventions, 77.8% were accepted. The percentages were: duplicity (30.9%), modification DF/posology (23.8%), usual treatment not prescribed (7.1%), therapeutic exchange (7.1%), discontinuation medication due to allergy (7.1%), therapy reconciliation error (4.8%), reconciliation on admission (4.8%), information (4.8%), additional treatment (4.8%), prescribing error (2.4%), unnecessary medication (2.4%). Of the accepted interventions, 11.9% were related to high-risk medicines according to the Institute for the Safe Use of Medicines<sup>1-2</sup> (nonsteroidal anti-inflammatory drugs (NSAIDs), beta-blockers, heparin, immunosuppressants). Of the not-accepted interventions, 50.0% corresponded to errors in home treatment reconciliation.

**Conclusion and relevance** The data obtained demonstrate that clinical interventions performed by the hospital pharmacy resident have a high degree of acceptance, increasing the quality and safety of healthcare and avoiding medication errors.

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**Conflict of interest** No conflict of interest

#### 5PSQ-130 DOSE BANDING OF INTRAVENOUS 5-FLUOROURACIL, OXALIPLATIN, PACLITAXEL AND GEMCITABIN: EVALUATION OF EFFICIENCY AND SAFETY SUBSEQUENT TO AN IMPLEMENTATION PROGRAMME

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**Background and importance** Dose banding (DB) is a strategy used to optimise the individualisation of antineoplastic treatments in order to reduce dose errors and achieve the highest efficiency.

**Aim and objectives** The aim of this work was to implement a DB system and analyse its impact on the efficiency and safety of patients treated with 5-fluorouracil (5-FU) elastomeric pumps and oxaliplatin, paclitaxel and gemcitabine solutions.

**Material and methods** Retrospective 5-month study, including 147 patients treated with antineoplastic agents (44 with 5-FU, 28 oxaliplatin, 36 paclitaxel and 39 gemcitabine). 5-FU was prepared in an elastomeric pump (Autofuser UFSC-2); the remaining drugs were prepared for infusion with NaCl 0.9% in a Freeflex plastic container.

Patients were divided into two groups for each drug, depending on the theoretical calculated doses adjusted to their body surface area (BSA): P1 higher-doses, P2 lower-doses. Dose-range was established with a  $\pm 5\%$  variability.