Conclusion and relevance The pivotal publications of RCTs of orphan drugs met most of the items in the CONSORT 2010 guidelines, particularly the abstracts. However, many pivotal CT were not randomised and compliance with the guidelines was not as high as that of other high impact journal publications. Therefore, more quality and transparency criteria should be required in pivotal CT publications of orphan drugs, such as randomisation, detailed masking and where to locate the complete protocol.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-015 COST OF STOCKOUT. A GROWING PROBLEM

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Background and importance In the past few years, medicines stockout has become a main problem in hospital management systems. To resolve this situation, different alternatives have to be used, taking resources from other commercial laboratories located in or out of the country through the health ministry. This directly affects demand and price, and most times these cannot be quantified.

Aim and objectives To quantify the cost of using other commercial laboratories as an alternative to cover medicines stockout in a local hospital.

Material and methods A review of those medicines out of stock during the period January 2016 and October 2019 was made. In order to achieve this goal, the database of the Spanish Agency for Medicines and Health Products (CIMA), Foreign Medicines database and the Andalusian Health System purchases system (SIGLO) were used.

Results During the study period, the CIMA recorded 1044 notifications of stockout, of which 146 affected purchases in the pharmacy service: 3 (2.05%) in 2016, 6 (4.11%) in 2017, 30 (20.55%) in 2018 and 107 (73.29%) in 2019, with 32 cases having a direct economic impact (15 by requesting foreign medicines and 17 by changing to an alternative).

The increase in cost due to ordering foreign medicines was 20 332.55€ while the increase produced due to a laboratory change was 58 868.12€ for the 4 year period, representing 0.5% of the total amount of purchases during that period.

The drugs that had the greatest economic impact, due to purchase from another national laboratory that was more expensive, were piperacillin/tazobactam (37.24% of the total cost increase), docetaxel (25.64%) and paclitaxel (17.16%). In the case of purchases of foreign medicines, the drugs with the greatest economic impact were intravenous levothyroxine (34.77% of the total cost increase) and docetaxel (25.42%).

Conclusion and relevance Stockout is a growing problem in our hospital management. Based on our study, this generates an increase of 0.5% in our total purchases in a 4 year period. Greater input from the competent authorities is mandatory to avoid this problem.

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No conflict of interest.

2SPD-016 FUTURE DISTRIBUTION MODELS FOR PAID PHARMACEUTICALS: THE PATIENT'S PERSPECTIVE

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Background and importance In Denmark, some expensive pharmaceuticals are given to patients for free by the hospital (paid pharmaceuticals, PP). A total of 35 000 patients receive PPs from the hospitals in the Central Denmark Region, either by picking them up from the hospital ward or by shipment from the hospital pharmacy. In the near future, the hospital pharmacy will be required to handle all PP deliveries. To ensure high quality and that patient needs are met, the distribution model has been reworked.

Aim and objectives The objective was to identify patient needs and preferred delivery model for the distribution of PPs.

Material and methods In an electronic questionnaire, patients were asked to prioritise five predefined factors for distribution of PPs. For example, "there is a maximum of 25 km to the pickup spot" or "possibility for pick up at all hours" (it was possible to prioritise more than one factor). Furthermore, patients in the habit of picking up PPs at the hospital ward (n=145) were asked to evaluate the importance of being able to converse with a healthcare professional (HCP) when picking up the medication.

The questionnaire was distributed to patients from different hospitals around the Central Denmark Region, receiving PPs.

Results A total of 190 patients responded to the questionnaire. Of the five predefined factors, 47% prioritised "there is a maximum of 25 km to the pickup spot" and 47% "I can pick up PPs when going for a scheduled visit at the hospital ward"; 40% choose "possibility for pickup at all hours"; and 26% choose "I can converse with a HCP when picking up PPs" and "next of kin can pick up my PPs".

Other factors, identified by the patients, were: "possibility to park my car", "home delivery", "discretion" and "larger quantity in each delivery".

Asked specifically, 55% choose "important" or "sometimes important" when asked the importance of speaking to a HCP; 35% could not imagine having such a conversation by phone.

Conclusion and relevance Distance to the pick up spot and flexibility in the hours available for pick up were identified as important factors for patients receiving PPs. These are important findings and will be taken into account when decisions are made on the future distribution model for PPs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-017 IMPACT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE AT THE LISBON PORTUGUESE INSTITUTE OF ONCOLOGY (FG, EPE)

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Background and importance To prevent the introduction of falsified medical products into the supply chain, on 9 February 2019, the directive 2011/62/EU was applied. This legislation

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has allowed the implementation of measures to ensure authenticity and a high level of traceability, providing greater patient safety.

Aim and objectives To assess the impact of the implementation of the falsified medicines directive 6 months after introducing the new legislation.

Material and methods Elaboration of a form (MS-Excel) with the purpose of systematising the data was performed. Of all products prescribed between 18 and 27 September 2019, products not covered by the requirement of a unique identifier code were excluded. The following parameters were analysed: presence of the unique identifier code, start time and end of code scan, and appearance of problems with the scanning procedure.

Results A total of 201 products were analysed. About 69% of the products had a unique identifier code. Of the products intended to be dispensed for outpatients, only 70% had a unique identifier. After reading 10 935 packages, it was found that, on average, reading of 12.9% of the products with a unique identifier code had at least one scanning issue. The average time for reading a unique identifier code was 9.5 s (includes connecting the software, verifying the safety device, positioning the packaging for the scan read and waiting for scan read confirmation).

Conclusion and relevance Six months after introducing the counterfeit medicines directive, about 31% of the products received in the hospital pharmacy did not have a unique identifier code. This includes products for outpatients where scanning at dispensing could be a relevant added value. Reading time of the unique identifier code represents around 29 working hours in 8 working days, or 0.5 ETC (7 hour working day). Implementation of this directive required investments in software, material and human resources, and the internal work procedures were also reorganised. Direct advantages for patient care are not yet evident as the unique identifier is still not fully implemented.

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No conflict of interest.

2SPD-018 FOUR YEAR STUDY OF DRUGS SHORTAGES IN TWO PUBLIC HOSPITALS

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Background and importance Drugs shortages are becoming a public health issue. Public hospitals are meant to buy drugs through purchasing groups which give relevant data on shortages.

Aim and objectives Data from two hospitals of different sizes and from different purchasing groups were compared to build a regional view of shortages.

Material and methods A 4 years retrospective study was carried out using data from a university hospital (3000 beds), from its purchasing group and from a public neighbouring hospital (1800 beds) of another purchasing group. Different indicators were calculated: unavailability profile (shortage; quota—quantitative or qualitative— limitation of delivery and issues), median duration and availability rate of an alternative drug. Data were then compared between the purchasing group and the university hospital, and between the hospitals, using the Student's t test.

Abstract 2SPD-018 Table 1

	Purchasing group	University hospital	Neighbouring hospital
No of unavailable drugs (rate of shortages; quotas; issues)	1016 (80.71%; 12.89%; 6.40%)	678 (80.38%; 18.88%; 0.74%)	620 (79.68%; 15.81%; 4.52%)
Median duration in weeks (shortages; quotas; issues)	4.71 (4.57; 8.28; 4.42)	8 (6,29; 19,21; 5,57)	7.64 (6,54; 11,57; 20,14)
Presence of an alternative drug (rate)	67.39%	33.19%	33.44%

Results Between the purchasing group and the university hospital, there were significant differences for each indicator ($p<0.0001$). Regarding the hospitals, there were only significant differences for the unavailability profile ($p<0.0001$) and median duration ($p=0.0405$).

Conclusion and relevance The significant differences regarding the unavailability profile may be due to the lack of common definitions on shortages. The behaviour of the manufacturers regarding the size of the hospital might be another reason as the mediation duration was different between the hospitals. Quotas were two times longer than regular shortages, but they put more strain on teams and led to the consideration of the ethical aspects of the dispensation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-019 FOUR YEARS OF SHORTAGES REGARDING THE ANATOMIC, THERAPEUTIC AND CHEMICAL CLASSIFICATION

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Background and importance Drugs shortages are becoming more important. It is necessary to gather specific data in order to mitigate the effects.

Aim and objectives Data from a national purchasing group were analysed to build a national view of shortages and their evolution regarding therapeutic area.

Material and methods A 4 year retrospective study (1 June 2014 to 31 May 2018) was undertaken using data from a national purchasing group and consolidated with data from an adherent hospital. Different indicators were calculated using the anatomic, therapeutic and chemical (ATC) classification: unavailability profiles (shortage; quota—quantitative or qualitative—limitation of delivery; and issues), number of recurrences, median durations and unavailability rates (number of shortages divided by number of drugs available in an ATC class).

Results Each ATC class was studied (1305 drugs); 5 had the most impact (table 1).

A peak occurred in 2017 for all classes, except V class. In J class, there was a lack of penicillin combinations (seven drugs) in the first quarter of 2017, and at the end of the

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