Background and Importance Erenumab is a new monoclonal antibody for the treatment of migraine that binds to the calcitonin gene-related peptide (CGRP) receptor to inhibit its function. Erenumab is a drug with a considerable economic impact on the hospital's annual budget.
Aim and Objectives To evaluate the budgetary impact of the redosification of the commercial dose of erenumab 140 mg into doses of 70 mg.
Material and Methods An observational, retrospective study was conducted in a tertiary care hospital with a clean room. All patients treated with erenumab between 1 January 2019 and 30 August 2022 were included. The variables collected were: sex, age, dose prepared per patient, number of redoses per patient, and number of syringes of erenumab used. To calculate the budgetary impact of erenumab, a pharmacoeconomic study was carried out in which the savings obtained by the redosification of 140 mg in doses of 70 mg were evaluated since both commercial presentations have the same price (PTR erenumab 70 mg and 140 mg = € 200). The actual cost of the treatments with redosing and the theoretical cost without redosing were calculated, considering the number of doses and the duration of treatment in each patient. The information was obtained from the corporate prescription programme and patients' clinical records.
Results A total of 281 patients were treated with erenumab during the study period. The mean age was 46 years (range 17-75), 86.8% (n=244) women and 13.2% men (n=37). A total of 1,133 syringes of erenumab 70 mg (mean: 2; range 0-29) and 1,875 of 140 mg (mean 4; range 0-28) were consumed. The real annual cost of the treatments with redosing was € 519,827; compared to a theoretical annual cost of € 629,282 if the redosing had not been carried out. Therefore, the redosification of erenumab 140 mg into 70 mg has saved 547.28 syringes of erenumab 140 mg per year (€ 109,455). An estimated saving of € 389.52 per patient was obtained by the redosification of erenumab 140 mg dose into 70 mg.
Conclusion and Relevance The results show that the repackaging of the 140 mg dose into 70 mg is a great economic saving practice and easy to implement in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

3PC-005 CLOSED SYSTEM TRANSFER DEVICE (CSTD) EXTENDS PRACTICAL IN-USE SHELF LIFE TO 28 DAYS AFTER FIRST PUNCTURE OF NON-PRESERVED SINGLE-USE-VIALS IN BOTH CONTROLLED AND UNCONTROLLED ENVIRONMENTS

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Background and Importance Closed system transfer devices (CSTD) were originally designed to protect operators from cytotoxic, mutagenic, and reprotoxic agents. There is increasing pressure to reduce cost burden by preserving drugs, especially in the field of oncology. One solution is drug vial optimisation, which can be accomplished by extending the practical beyond use date of drug vials, through use of CSTDs.
Aim and Objectives This study aimed to test if the Chemfort™ CSTD can maintain microbiological integrity after 10 withdrawals from vials over a period of 28 days.
Material and Methods Tests were performed in both a controlled GMP Class A environment and an uncontrolled environment (350 vials in each environment). Environmental conditions were monitored by continuous air sampling. The rubber stoppers of all vials, containing tryptic soy broth (TSB) growth medium, were disinfected prior to mounting Chemfort™Vial Adaptors (VAs) on the vials. The Chemfort™Syringe Adaptor (SA) was attached to a 10 mL syringe and subsequently connected to the VA. The septa of both the VA and SA were disinfected prior to every connection. Ten 5 mL aliquots were withdrawn from each vial at 2-week intervals (days 0/3 syringes, 14/3 syringes, and 28/4 syringes), incubated for 7 days at 20–25°C and then 7 days at 30–35°C. After 28 days, the vial containing the remaining growth medium (50 mL) was also incubated for 7 days at 20-25°C and then 7 days at 30-35°C. Vials and syringes were inspected visually for signs of microbial growth during each incubation. Ten positive control containers were subjected to a growth promotion test.
Results No signs of microbial growth were observed in any of the 7,000 samples, nor in the growth medium remaining in the vials after transfers were performed in either an uncontrolled or controlled environment.
Conclusion and Relevance The data presented demonstrates the ability of the tested CSTD to maintain microbiological integrity and support the decision to extend the practical in-use shelf life of drug products for up to 28 days when used with Chemfort™ in either aseptic conditions or uncontrolled conditions.

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3PC-006 CONTAINER CLOSURE INTEGRITY TESTING AND PROCESS VALIDATION OF CLOSED SYSTEM TRANSFER DEVICES FOR ASEPTIC RECONSTITUTION OF DRUG VIALS CONNECTED TO FLUID BAGS

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Background and Importance The closure integrity and process validation of closed system transfer devices (CSTD) should be assured before implementation in clinical settings. However, there are no gold standard methods for Container Closure Integrity Testing (CCIT) of CSTDs.
Aim and Objectives We aimed to investigate the closure integrity and validate the aseptic procedure of two types of CSTDs (Vial-Mate from Baxter, hereafter called CSTD A and Ecoflac Connect from B. Braun, hereafter called CSTD B) by using a combination of the dye ingress test and a media fill test.