Results According to the product information, an implant releases FAc for a maximum of 36 months, and an additional implant can be placed after 12 months if vision decreases or retinal thickness increases. Pivotal studies and the IRISS observational study concluded in the need to use 1.3 implants/eye and 1.13 implants/eye affected during the first 3 years respectively, this last value being the one considered by the ERG (Evidence Review Group). Taking this last reference, the cost of treatment/affected eye at € 1558.84/eye/year or € 4676.53/eye/3 years.

To estimate the target population, we used the criteria of the SMC evaluation report in which they considered a total of 179 patients with pseudophakic chronic DME eligible for treatment in the first year, increasing to 186 in the fifth year. Unlike the SMC, our NHS restricts its funding to third-line, after anti-angiogenic agents and in patients with a suboptimal response to various intravitreal dexamethasone implants or pseudophakic patients.

Making a parallelism with the Scottish population, 33.5 patients/1st year–34.8 patients/5th year would be candidates to receive FAc in our region.

NICE and the ERG found that in clinical practice 35% of patients would require bilateral treatment. Thus 12 patients/year would need treatment in both eyes in our population. The economic impact in our region would range between € 5,3000.56/year if it were inserted in only one eye and € 71,706.64/year in both eyes.

Conclusion and Relevance The financing conditions of our NHS position the drug in the third-line, which in a certain way contains the budget impact.

Since SMC restricting the conditions of use more than our NHS, the budget impact could be underestimated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-005 NEW CLOSED SYSTEM TRANSFER DEVICE CONTAINS REAL DRUG VAPOURS FOR UP TO 28 DAYS

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10.1136/ejhpharm-2023-eahp.18

Background and Importance Several Closed System Transfer Devices (CSTDs) are currently approved a 7-day usage period. Increasing pressure to reduce drug costs and data supporting stability of some drugs beyond 7 days create a demand for CSTDs that contain hazardous drug vapours for 28 days. A previous study proved that a model air-cleaning CSTD contains drug vapours for 7 days.

Aim and Objectives The aim was to test drug vapour containment of an air-cleaning CSTD under extreme conditions for 28 days.

Material and Methods Cyclophosphamide (CP) was chosen as the representative drug. A model CSTD (Chemfort™) Vial Adaptor (VA) was connected to each vial, and CP was reconstituted using the CSTD Syringe Adaptor. VAs at the end of their shelf life, representing extreme conditions, were tested both immediately following and 28 days after reconstitution, with and without intact Toxi-Guard® air-cleaning systems (an integral part of the Chemfort™ VA).

Each vial was transferred to a closed test chamber connected to a vapour trap. To increase drug vapourisation, the chamber was heated to 50°C and nitrogen gas was constantly introduced into the vials. Any vapours potentially released from the Chemfort™ VA were trapped and then extracted with solvent.

Quantification of CP was performed using a validated LC/MS/MS method.

Results No CP was detected for any of the VAs with intact Toxi-Guard® components, whether tested immediately or 28 days after reconstitution, even when heat and gas flow were employed to encourage the production of vapours and when the VA was at the end of its shelf life. The limit of detection of the method was estimated at 0.02 ng. Without an intact Toxi-Guard®, 110.3 ng of CP were released into the environment.

Conclusion and Relevance The model CSTD utilising Toxi-Guard® air-cleaning technology contained drug vapours after a 28-day usage period, even under extreme conditions. A recent study proved 28-day prevention of microbial ingress by the same CSTD. Taken together, the two studies support pharmacists' decision to use drugs for their full shelf life or to extend the beyond-use-date up to 28 days when using an appropriate CSTD, thus reducing cost and waste.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

Ofer Raz and Elana Slutsky Smith are employed by Simplivia Healthcare Ltd, the manufacturer of Chemfort™. Dekel Navarro and Daniel Epstein declare no conflict of interest relating to the material presented in the abstract. Funding for this project was provided by Simplivia Healthcare Ltd, the manufacturer of Chemfort™.

2SPD-006 ARE ALL BIOLOGIC AGENTS IN THE TREATMENT OF ANKYLOSING SPONDYLITIS EQUIVALENT ALTERNATIVES?

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10.1136/ejhpharm-2023-eahp.19

Background and Importance Nine drugs are currently approved for the treatment of ankylosing spondylitis (AS) in adults: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, upadacitinib and tofacitinib. Tofacitinib was the last of them to receive its approval. However, there are no direct comparisons between them.

Aim and Objectives To establish whether the drugs approved for AS in adults can be considered equivalent therapeutic alternatives (ATE) in efficacy in AS.

Material and Methods A search of clinical trials of these drugs in adult patients with AS was conducted, phase II or III, double-blinded, controlled with another drug or placebo.

Other inclusion criteria were

- Endpoint: ASAS40 (a ≥40% improvement and an absolute improvement from baseline of the Assessment in SpondyloArthritis International Society).
- Follow-up time: 12-16 weeks.