medications, of which 225 were pharmacy manufactured (17.5%).

Conclusion and relevance A Pub-Med search found studies dealing with the problem of unlicensed or off-label drugs in children, but no data were found evaluating the amount that is manufactured in the pharmacy. Our findings showed that individual pharmacy preparation in paediatrics is indispensable for the success of pharmacotherapy in critically ill children. It means that conditions were treatable that otherwise were not.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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IN USE PHYSICOCHEMICAL STABILITY OF PEMBROLIZUMAB UNDER THE DILUTION CONDITION REQUIRED FOR USE IN A DAY HOSPITAL

Background and importance Pembrolizumab is a monoclonal antibody widely used in the oncology field at a fixed dose of 200 mg. The stability of pembrolizumab diluted in 0.9% sodium chloride solution is 96 hours stored at 2–8 °C, as reported in the summary of product characteristics. Aim and objectives The purpose of the study was to evaluate the in-use stability of pembrolizumab diluted at clinically relevant concentrations and stored in polyolefin infusion bags over a 14 day period. There is a practical implication in compartmenting these solutions in advance, with a view to a strategic reorganisation and optimisation of work in an antiblastic drug preparation laboratory integrated into a day hospital system.

Material and methods Analysis was performed on three samples of pembrolizumab at a concentration of 2 mg/mL, stored at 2–8°C, on days 0, 1, 4, 7, 11 and 14. Analyses included pH, osmolality, turbidity, dynamic light scattering (DLS), size exclusion chromatography–high performance liquid chromatography (SEC-HPLC) and nanoparticle tracking analysis (NTA). These methods were selected on the basis of a preliminary study on samples subjected to mechanical and thermal stresses.

Results All samples were clear, without particulate or precipitates, and turbidity free. pH and osmolality did not reveal different results on day 14 compared with day 0. Using SEC-HPLC, only one peak was found corresponding to the monomer of pembrolizumab at about 150 kDa, with a retention time (Rt) of 16.27±0.02 and 16.41±0.08 at day 0 and day 14, respectively. No signs of aggregates or fragmentations were detected as Rt and the area under the curve of peaks remained constant over time. At all time points, DLS showed a monomodal sample with a hydrodynamic diameter of around 11 nm. These results were in agreement with NTA data.

Conclusion and relevance No physicochemical instability of pembrolizumab solutions was observed during the study period. Therefore, preparation of pembrolizumab in advance might be considered in the perspective of dose banding for a cost saving strategy, reducing the patient’s waiting time between evaluation and the beginning of treatment, and avoiding drug wastage. Maintenance of biological activity and lack of immunogenicity should be investigated to confirm these studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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