Background and Aims  The availability of appropriate medicines for pediatric patients remains a challenge in any Health System. To evaluate the extent of this limitation in Portugal, the INFARMED, I.P., conducted the present study aiming at 1) knowing which extemporaneous formulations were prepared/used in hospital settings and 2) identifying which of these have a liquid formulation medicine available in Portugal, EU or USA.

Methods  A cross sectional study was performed in nine Hospitals in Portugal regarding the collection of 2010 data on the use and production of extemporaneous formulations. The information was gathered through a questionnaire. Data analysis was restricted to medicines with more than 1000 formulations prepared or prescribed to more than 100 patients.

Results  Thirty three medicines met the defined criteria. They were included in groups A and C of the ATC classification (Alimentary Tract and Metabolism and Cardiovascular System) with 8/35 (24.24%) each, followed by Anti-infectives for Systemic Use and Nervous System with 5/35(15.15%) each. It was realized that 20 (75.76%) have a licensed oral liquid formulation either in Portugal, EU or USA. In Portugal 7 (21.21%) have or had a market authorization no longer available due to industrial ending. In addition, different hospitals prepare the same medicine in different formulations.

Conclusions  The results confirmed the needs of Portugal in this area, identified potential lack of interest of the industry and recommend that strong action should be taken by the Regulatory Authority in the implementation of industrial manufacture authorization of small GMP batches of these medicines.