agreed by the Paediatric Committee (PDCO) at the EMA in SLE in the period since the Paediatric Regulation came into force until today (2007–2022) to identify current challenges.

Results So far, the PDCO has evaluated 30 submissions for PIPs for (j)SLE. All PIP related products are also being developed for adult-onset SLE. So far 22 have led to an agreed plan correspond to 21 different active substances, each with a different mechanism of action. 4 of them are being specifically developed to target lupus nephritis.

The agreed PIPs focus on patients from 5 years of age, and on average each PIP includes only a single clinical trial (14 of them vs 7 with 2 and one with 4 trials). Of the 32 planned clinical trials included in the PIPs, 14 are RCTs versus placebo, as add-on to standard of care.

On average, a sample size of at least 83 patients was required in the main trial and 17 PIPs contained an agreed modelling and simulation analysis to support appropriateness of paediatric dosing and/or analyse pharmacokinetics/pharmacodynamics (PK/PD).

Belimumab was the first biologic treatment that obtained a paediatric indication for (j)SLE above 5 years of age in the EU. Extrapolation of efficacy data from adults and older paediatric patients eventually allowed regulators to grant an indication in the younger age groups.

Results from other PIPs are awaited.

The number of PIPs for the treatment of (j)SLE evaluated by the PDCO highlights a very competitive area where agreed developments are relatively consistent, but recruitment of paediatric patients seems to be challenging.

Conclusions Stand-alone developments might not deliver results and answer the most pressing research questions in the required timeframe. Therefore, innovative designs considering different mechanisms of actions, potential synergistic effects, potential prioritisation should be explored. Furthermore, research should also focus on bridging biomarkers, to make better use of extrapolation of efficacy from adults.

B) Session 4: New Activities Within ESDPPP: What We Have Reached after Liverpool 2022

5 CZECHPHARMPED: STARTING THE OPTIMIZATION OF PHARMACOTHERAPY IN CHILDREN IN DAILY CLINICAL PRACTICE IN THE CZECH REPUBLIC AND SLOVAKIA (INITIATIVE OF A NETWORKING GROUP OF YOUNG RESEARCHERS)

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Introduction Evidence-based (EB) data on drug dosage optimization in children are already available across Europe. However, their systematic translation was lacking in the Czech Republic and Slovakia. The purpose of our project is to create a Czech drug database (CzechPharmPed) based on evidence of already existing international databases and national specifics, that will have a positive impact on the daily clinical practice. The objectification of this impact is crucial, moreover, provides valuable feedback.

Methododology After the development of the content framework respecting drugs according to the State Institute for Drug Control (SÚKL) and technical development (a system based on PHP, MySQL and CSS, JavaScript technologies provided via a secure HTTPS connection, using HTTP 2.0 technology), the pharmacoepidemiology of paracetamol was evaluated using a cross-sectional study to map baseline values in a single centre.

Results In the pre-implementation analysis, of all paracetamol prescriptions, 8% of errors were found in the indication, 15% in the routes of administration and in 20% inaccuracy of the pharmaceutical form according to the manufacturer. The single and daily cumulative dose were correct for 59% and 70% of prescriptions, respectively. The SÚKL recommendation for prescribing paracetamol was used by 80% of caregivers, but 62% of these were found to be inaccurate for use in children. Therefore, the domains (www.pharmped.cz, www.pharmped.sk.) and the calculator in cooperation with the database iplprecept.cz (individually prepared medicines) were approved for implementation.

Conclusion CzechPharmPed is designed as a web-based, user-friendly, reflecting the need to update the user interface standards required in the Czech Republic and Slovakia while using the pre-implemantation analysis, its impact can be evaluated properly.

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6 REDUCTION OF RISKS IN THE MEDICATION PROCESS AFTER ADAPTING THE EMR-SYSTEM TO CHILDREN AND INTRODUCTION OF THE NATIONAL SWEDISH MEDICATION DATABASE FOR CHILDREN

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Introduction Drug treatment in children is complex with a high risk of medication errors. One of the most frequent medication errors identified are dosing errors, occurring in all parts of the medication process (prescription, preparation, and administration). The aim of this study was to evaluate interventions directed at reducing medication errors at Queen Silvia Children´s Hospital in Gothenburg, delivered through the electronic medical record (EMR). Between the two years in focus 2013 and 2020, the following changes were made:

- The introduction of a Clinical Decision Support System (CDSS) with weight-based dose calculation and Dose Range Check into the EMR.
- The integration of the national Swedish medication database for children ePed into the EMR, delivering experience- and evidence-based pediatric drug information with diagnosis-specific dose recommendations and standardised dilutions as well as relevant information for administration.