Formulating better medicines for children

Meeting Report: EuPFI Workshop on Improving the Administration of Paediatric Oral Liquid Medicines using Dosing Syringes and Enteral Accessories

EuPFI Devices Team | April 2019

The EuPFI Workshop on Improving the Administration of Paediatric Oral Liquid Medicines using Dosing Syringes was hosted by UCL at the School of Pharmacy on 11th September 2018.

Summary

A workshop was organised by the European Paediatric Formulation Initiative (EuPFI) in collaboration with the MHRA, as part of its mission to promote and facilitate safe medicines for children. The aim of the workshop was to find an optimal path towards the correct oral dosing of all paediatric patients with dosing syringes and enteral accessories (adaptors), that meets the requirements of patients, regulators, healthcare professionals (HCPs) and Industry. The event was a success with the contribution of more than 50 participants from all key stakeholder groups. There was lively discussion and debate on the challenges associated with the administration of oral liquid medicines to the paediatric population in both a hospital and home setting (dosing devices, dosing accuracy etc), with moving real-life examples.

Background and Workshop Content

While oral liquids are acceptable for the whole paediatric age range, a key challenge with their administration is to ensure the correct dose is measured. This issue was highlighted by Dr Sara Arenas, Consultant Pharmacist Paediatric Critical Care, Evelina London Children's Hospital and member of the EMA Formulation Working Group, who co-authored an investigation into the accuracy of syringes with commonly prescribed paediatric liquid medicines[1)].

The workshop agenda was put together by members of the EuPFI Devices Workstream and ensured that there was an opportunity for direct dialogue between Regulators, HCPs (Clinicians, Nurses and Pharmacists), Industry and Device manufacturers/suppliers on harmonized approaches that can provide acceptable dosing volumes to minimise errors across the entire spectrum of paediatric practice. Delegates from all over Europe attended the workshop on invitation.

The specific aims of the workshop were:

- To share current practices and challenges associated with the development, control and supply of oral dosing syringes and enteral accessories.
- To describe the requirements and regulations industry must comply with and how industry develops, selects or assesses the dosing syringe.
- To ensure all participants have an overview of the main issues users experience with the administration of oral liquid medicines to the paediatric population in both a hospital and domiciliary setting, including practical considerations.
- To review factors (e.g. users, environment, design and technical factors) that have an impact on accurate administration of doses routinely prescribed to paediatrics.
- To identify potential improvements which may be implemented to achieve a safer administration of medicines to the paediatric population.

The workshop was opened by Prof. Catherine Tuleu (UCL School of Pharmacy, EuPFI chair). Dr Smita Salunke (EuPFI CSO, UCL School of Pharmacy) reminded the delegates of the very reason why they were all there and emphasised that only by working together we can make a difference!

"Hope is not just a dream" said Dr Sara Arenas Lopez (Evelina London Children's Hospital, UK). "*We really need to sort this out since we feel that the syringes are not compatible with hospital practice requirements and harmonisation/standardisation of these devices is required."*

In the first session chaired by Dr Jenny Walsh (Jenny Walsh Consulting Ltd, UK) speakers representing HCPs, the pharmaceutical industry and device suppliers discussed the current practices regarding the development, supply and use of paediatric oral dosing syringes and enteral accessories. Several key themes were highlighted, for example the problems faced by HCPs when dosing small volumes and the requirement to use enteral accessories that need a different technique compared to dosing with an oral syringe alone, both of which can lead to dosing errors. In addition, the regulatory framework for oral administration devices is globally inconsistent and unclear which is a challenge for industry and device suppliers who spend significant resources on designing and testing devices to ensure they are suitably accurate and user-friendly. During this session, participants discussed the key challenges from different perspectives and ideas were brought forward to address them and facilitate the correct dosing of all paediatric patients.

The second session focused on regulatory perspectives and was chaired by Gareth Hilton (AstraZeneca, UK). The talks in this session gave an overview of current EU regulatory requirements and guidance, together with examples from daily practice of dosing small volumes and the associated challenges and problems/failure modes. The potential danger of inadvertently injecting oral or enteral liquids prepared in parenteral syringes was emphasised and safe practice recommendations shared.

In the afternoon, delegates participated in an interactive breakout session (led by Gareth Hilton (AstraZeneca, UK), Paul Blowers (AbbVie, USA) and moderated by Esmerald Hermans (Janssen, Belgium) and Jenny Walsh (Jenny Walsh Consulting, UK)). During this activity, delegates discussed some of the challenges they had personally faced. For example, the enteral accessories (adaptors) that must be used in hospitals may not be compatible for use with the dosing devices and products developed and supplied by Industry. The supplied oral dosing devices are therefore often discarded

by hospitals, and alternative generic devices used instead, which may have sub-optimal low dose volume accuracy for the product. Delegates then brainstormed on potential solutions to the problems that had been identified.

Finally, participants voted on potential solutions that were considered to have the highest impact on the safe and effective administration of oral liquid medicines to children. The harmonisation/ standardisation of oral syringe designs globally was deemed to be a key priority as well as the improvement of the accuracy of dosing small volumes.

Overall feedback from delegates was very positive; there had been the opportunity to learn about other stakeholders' perspectives and have cross-functional meaningful discussions on the topic.

Actions from the workshop

During the workshop the new ISO 20695 draft standard on enteral feeding systems was discussed and reviewed. Concerns were voiced regarding the absence in the standard of dosing accuracy requirements or references to standards which describe dosing accuracy. Participants agreed a letter should be sent to the ISO group to highlight these concerns. A letter was sent by EuPFI to the Chair of CEN/TC205 on 30 November 2018 and has subsequently been shared with the British Standards Institution (BSI).

In addition, a paper detailing the discussions from the workshop will be submitted for publication in the European Journal of Pharmaceutics and Biopharmaceutics. The aim is to create a better awareness of possible issues and hurdles in dosing small volume liquids and enable stakeholders to define better practices, materials and standards.

1) *Accuracy of enteral syringes with commonly prescribed paediatric liquid medicines by Sara Arenas-Lopez, Karuna Gurung, Shane M Tibby, Miguel Angel Calleja Hernandez, Catherine Tuleu, ADC Online First, published on February 24, 2017*