Advanced Drug Delivery Reviews 73 (2014) 1

Contents lists available at ScienceDirect

Advanced Drug Delivery Reviews

journal homepage: www.elsevier.com/locate/addr

Preface

Paediatric drug delivery☆

Medicines for children should be presented in dosage forms appropriate to the age and ability of the baby, child or young person and should accommodate the requirement to adjust dose according to changes in age or size. If this can be achieved, adherence to treatment and clinical outcomes should improve and medicines can be used both safely and effectively.

In contrast to older people, most children are generally healthy and do not require medicines (with obvious exceptions for common illnesses involving infection, fever and pain for example). The incentive for the industry to research and develop age-appropriate medicines for those smaller numbers of children with conditions more commonly seen in adults has been lacking and issues such as cost and ethics of research and development have been raised. Legislation in Europe and USA is now quite clear in requiring and rewarding the industry to research and develop medicines for children, when there is an unmet therapeutic need, at the same time as for adults [1,2].

Inevitably there has been a focus on the pharmaceutical needs of children with a reflection paper [3] and then a guideline on pharmaceutical development [4] coming into force in Europe in February 2014. Formulation initiative collaborations have been established in Europe and USA and research funding and publications in this area have increased [5]. The Global Research in Paediatric (GRiP) initiative [6] has established a work stream on paediatric formulations and has included a module on the subject in developing teaching to improve the numbers of professionals trained in paediatric clinical pharmacology and the design and conduct of clinical trials. A series of webinars on topics of current interest have attracted 100 participants from medical, nursing and pharmaceutical disciplines from many different countries.

The focus on development of medicines for children has unveiled the requirement for a better understanding of 'age-appropriateness' and the application of established and developing pharmaceutical technologies in the younger age groups. Perhaps most challenging is the major increase in studies in neonates which has exposed our lack of knowledge of the safety of excipients and their handling by the immature but developing physiology [7].

Wider questions of health economics have also come to the fore and may influence future developments. Are some of the new technologies affordable even by the economies of developed countries? Are there established paradigms that should be challenged that might be relevant, for example at what age can children take traditional monolithic tablets? Can the requirement to avoid excipients of concern and for flexible dosage be satisfied by mini-tablets or multi-particulates at prices deemed 'affordable'? What is the role of masking taste at the point of administration by addition to food or drinks? Is there a role for verified manipulation of dosage forms at administration or in advance by compounding by the pharmacist when paediatric formulation will be technically difficult or costly?

This issue of ADDR reviews many of the problems identified and the solutions introduced or under development.

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☆ This preface is part of the *Advanced Drug Delivery Reviews* theme issue on "Drug delivery and the paediatric population: where are we at?".

http://dx.doi.org/10.1016/j.addr.2014.05.013
0169-409X/