The well-known paediatric therapeutic disasters of the late 1950s (sulfisoxazole, chloramphenicol) revealed the need and gave the impetus for the development of paediatric clinical pharmacology. Despite the fact that training of paediatric clinical pharmacologists has been going on for decades, training capacity remains very small. Consequently the number of trained paediatric clinical pharmacologists in the world is counted in the hundreds, with the majority of countries having 10 or fewer [1, 2].

Today, the need for more and better development, scientific study, regulatory assessment and appropriate use of paediatric medicines has been recognized in the US, EU, and WHO paediatric medicines initiatives. Implementation of all the paediatric studies mandated by these initiatives requires well-trained investigators and other experts (e.g. research trained nurses, pharmacists, laboratory scientists), which in many countries do not exist in numbers sufficient to embrace the demands associated with paediatric drug development. Accordingly, building enhanced capacity and strength in paediatric clinical pharmacology across the world is essential to ensure the success of these initiatives.

**Definition of Paediatric Clinical Pharmacology**

Paediatric Clinical Pharmacology can (in reference to the Definition of Clinical Pharmacology; Page XXX) be defined as a scientific discipline that involves all aspects of the relationship between drugs and humans during growth, development and maturation. Its breadth includes the continuum between discovery, development, regulation and utilization of medicines (as regards compounds and formulations) intended to benefit the paediatric population. As well, paediatric clinical pharmacology is concerned with the response to and adverse effects of medicines, their misuse and the economics of drug therapy as one avenue for restoring and/or promoting child health. As the great majority of scientific research and drug development is for many reasons first done in adults, paediatric clinical pharmacology adds the translational element of adopting scientific methods and translating scientific information from adults to paediatric patients.

It is recognized that by virtue of the comprehensive scope of paediatric clinical pharmacology, it represents a discipline that must be multi-disciplinary by design, involving a myriad of skills and relevant individuals with these skills who are involved in one or more scientific and/or clinical facets of the discipline (e.g., physicians, biomedical scientists, non-physician health care providers such as nurses and pharmacists). Paediatric Clinical Pharmacology *per se* is therefore generally not recognized as a profession but rather, a multi-faceted field of endeavour which constitutes a scientifically driven professional discipline which is dependent on a wide variety of highly skilled professionals who are both educated and trained in a comprehensive and complete fashion.

**Scope of Practice in The Field of Paediatric Clinical Pharmacology**

Practice environments for Paediatric Clinical Pharmacology are diverse and can include patient care, research, teaching, drug development, and drug regulation (see section 6 Roles of Clinical Pharmacology; Page XXX). Paediatric clinical pharmacologists may participate directly in care of paediatric patients as either primary care givers or consultants, or by working in scientific and/or administrative capacities to improve the quality of medicines use in all health care settings, irrespective of the wealth of the country. At the country level, paediatric clinical pharmacologists can provide valuable services in the development of a National Medicines Policy that in part would ensure that necessary measures to protect the basic human rights of paediatric patients who participate in medicines research are developed and maintained. Their involvement often extends to the regulatory assessment of paediatric medicines, the development of national treatment guidelines, proposing inclusion of paediatric medicines in reimbursement lists, and monitoring of the performance of medicines in real life after regulatory approval (e.g., through the application of pharmacoepidemiology, pharmacovigilance and pharmacoeconomic principles) to assess impact on health outcomes.
It should also be recognized that globally, more than a third of the population in developing countries, and almost half in the least developed countries are in the paediatric age range (less than 18 yrs), and close to 9 million children die every year before their 5th birthday in diseases mostly amenable to treatment. In the area of priority diseases like HIV/AIDS, malaria and tuberculosis, children lag far behind in access to appropriate medicines, especially where the majority of disease burden is borne by the paediatric population (e.g., malaria). Recognizing that children represent the hope of 100% of the world for its future, it is essential that their special needs with respect to the development and implementation of safe and effective drug treatment be fully embraced. To this end, the enhanced availability of the expertise and services that can be provided by paediatric clinical pharmacologists represents a critical need on a global level.

Training in Paediatric Clinical Pharmacology

Paediatric clinical pharmacology is a sub-discipline of clinical pharmacology and paediatrics. At present, it is a recognized paediatric medical subspecialty in the UK [3] and Australia. While many of the professionals in the world recognized as paediatric clinical pharmacologists have completed both medical education and formal training programs in paediatrics and clinical pharmacology, it is important to note that individuals outside of the profession of Medicine (e.g., biomedical scientists, professionals with degrees in Pharmacy, Dentistry, Psychology) who have also completed formal training in Paediatric Clinical Pharmacology and received certification through examination by country-specific credentialing boards have made significant and important contributions to the discipline from within its ranks. It is this professional diversity that enriches the discipline and will enable it to embrace the challenges of the future. Thus, it is critical that the development of training programs in paediatric clinical pharmacology be multi-dimensional in scope and appropriate for the professional skill set of qualified individuals who enter training.

Finally, it must be emphasized that the value of training in paediatric clinical pharmacology extends beyond the development of specialist paediatric clinical pharmacologists. It is vital that educational curricula for all health care professionals involved in the treatment of infants and children contain instruction in the principles of paediatric clinical pharmacology. Similar educational components should also be included in paediatric medical and surgical subspecialty training programs. The continued development of programs and practitioners of paediatric clinical pharmacology is essential for these broad educational goals to be accomplished throughout the world.

References:

