Medical writing in paediatrics: Children and the future

Elise Langdon-Neuner

Editor, *Medical Writing*

Editorial

Correspondence to:

editor@emwa.org

'Children are one-third of our population and all of our future.'

Select Panel for the Promotion of Child Health, 1981

With the falling birth rate I wonder if they still are a third of the population, but there is no doubt that they are our future. In drug research, however, recognition of the importance of differentiating children from adults has been tardy. Graham Blakey, in his pharmacokinetics series in this issue, explains how pharmacokinetics changes with age and discusses dosing for children. He emphasizes that children are not 'small adults' and cites alarming figures: around 70% of the medicines given to the paediatric population and 93% of the medicines given to critically ill neonates remain unlicensed or are used off-label. It is only now that regulators are forcing researchers to consider children in their own right. Under new EU legislation, the paediatric investigation plan (PIP), research is required to be conducted in children so that in future dosing regimens meet their specific needs.

This issue of *Medical Writing* (*MEW*) focuses on the recent EU legislation and all its ramifications for medical writers, and reflects the 'paediatrics and vulnerable populations' focus of EMWA's 34th conference, which was held in Cyprus in May this year. The issue gathers together material from some excellent presentations at the conference. EU legislation now requires that an applicant for marketing approval of any drug must have a PIP or a waiver in place. This plan or waiver needs to have been agreed with the European Medicines Agency (EMA). Three articles in this issue concentrate on different aspects of developing drugs for children, and negotiating and preparing applications for a PIP or waiver.

Klaus Rose, a consultant specializing in paediatric drug development, has experienced an increasing involvement of medical writers in designing overall plans in paediatric drug development and negotiating a programme with regulatory bodies. Very much with the medical writer in mind, he explains the background to the current legislation in Europe as well as that of its equivalent in the USA. He suggests the questions that need to be considered when developing a drug that is intended for use in children and explains the phases of the PIP life cycle. His article also touches on the special aspects of clinical trials in children and what the future holds for paediatric drug development, bearing in mind the high research costs involved.

Paolo Tomasi from the EMA provides guidance in his article on increasing the chances of securing a rapid and positive outcome of the application procedure. Medical writers will find his tips very useful, especially his discussion of applicants' frequent misunderstandings and mistakes.

Douglas Fiebig, an experienced medical writer in the field and EMWA veteran, tackles more specific aspects of writing the PIP application and planning the resources and timelines.

We are also pleased to publish two articles based on important presentations at the EMWA conference that cover more general aspects of medical writing. Mick Foy from the British Medicines and Healthcare products Regulatory Agency (MHRA) reports on the European medicines legislation which aims to improve pharmacovigilance. This legislation will bring about the biggest changes since the current system was created in 1995 and the article provides a starting point for medical writers to get to grips with the new procedures. Again concentrating on the medical writer's perspective, Theo Raynor gives some insight into his research at Leeds University in the United Kingdom on presenting information to patients. He seeks to establish what sort of information patients want and how this information can be written and delivered so as to be accessible and understandable. His investigations cover user testing, readability, and risk communication. An important aspect for the public is 'benefit', where there is still a long way to go in providing information despite specifications that it be included. Theo emphasizes that people need to be able to balance the chance of benefit from taking a

DOI: 10.1179/2047480612Z.00000000032

medicine against the risk of harm, but his research suggests that including 'benefit' information in numerical terms may pose problems for the industry because when the benefit is so presented patients think it too low.

Although Theo writes about how to present information to patients, the concept of patients as passive consumers of information is becoming a thing of the past. Ursula Schoenberg's article on crowd sourcing describes a fascinating revolution in which patients are not only discussing health problems and creating support groups on the web, but are also initiating their own studies.

The importance of the web for medical writers and their businesses has not been forgotten either in this issue of *MEW*. Bilal Bham has written a dummies' guide for medical writers who have not yet exploited the possibilities offered by networking websites like LinkedIn and Twitter®. And after you have mastered this you might like to progress to promoting your business with an online video presentation. All you will need is a camcorder and a laptop, as Phil Moran explains in his article on the moving image and your business.

Indeed, EMWA has its own example of video promotion. In a short video on EMWA's homepage (www.emwa.org) Helen Baldwin, an EMWA past-president, talks about medical writing as a career and about the Association in general. Adam Jacobs, another EMWA past-president, has put together a podcast, which reveals the variety of careers open to medical writers (see box, below).

Returning to the 'children' theme, Melanie Price and Diana Raffelsbauer discuss what must be the most controversial disorder to emerge in childhood, attention deficit/hyperactivity disorder (ADHD). Questions of cause and possible treatment which were not raised when children such as Fidgety Phil in Heinrich Hoffman's book '*Struwwelpeter*' (Shock-headed Peter) were chided for being naughty are now asked under the auspices of ADHD. But is ADHD a true neurodevelopmental disorder? The reviewer of this article who runs a society for ADHD sufferers and their relatives applauded Melanie and Diana's comprehensive and fair discussion of the current literature.

Children are our future, and among the children of today are the scientists of tomorrow. It is therefore fitting that we publish an article from a promising young scientist in this issue. Cameron Hamilton won a well-deserved prize for his essay entitled 'Are stem cells the future of healthcare?' The informative and clear style of the article is certainly on my wish list for the future of science writing.

Medical writers' work: Podcast from EMWA conference

At the EMWA conference in Cyprus, I kept a little audio diary of the conference, in which I talked to various medical writers about their work. No two medical writers I talked to had the same job, showing what a beautifully varied profession medical writing is. If you'd like to listen to the diary as a podcast, you can download it at http://dianthus.co.uk/emwa-conference-podcast. The full version lasts about 48 minutes, but if you're short of time, there's also an edited version which lasts just under 10 minutes.

Adam Jacobs
ajacobs@dianthus.co.uk