



Message from the President

by *Helen Baldwin*

I'm really thrilled to be writing my first President's Message for this issue of *TWS*! I have been EMWA Vice President for the last 2 years and then became President at our recent conference in Ljubljana. It's a great honour for me to take on this job for the next 2 years. I will do my best to ensure that EMWA continues to be the successful organisation that it is today and goes from strength to strength as our profession continues to grow and develop.

I will be supported by our new Vice President, Laurence Auffret. Laurence and I have much in common, for example I am British and live in France whilst she is French and lives in England. I think most people could understand why a girl like me, who grew up in rainy England, decided to move to the sunny South of France...but why on earth someone would choose fish and chips in Manchester instead of 'moules frites' in Brittany is something I hope to find out during the next 2 years of working with Laurence! We also have 3 other new EC officers: Laura Hollyhead as Honorary Secretary, Andrea Palluch as Public Relations (PR) Officer, and Gillian Pritchard as Treasurer. I would like to thank them all very much indeed for generously agreeing to dedicate some (but hopefully not all) of their spare time to EMWA over the next 2 years. I would also like to thank the other EMWA members who responded positively to our email asking for EC candidates and who are now helping on our subcommittees.

With around 900 members today, EMWA is still growing fast, and the challenges behind the scenes to keep the association running smoothly are substantial. Nevertheless, EMWA is in excellent shape and I feel very confident taking over the helm of this ship under such fair-weather conditions! There are several people who deserve a special mention here as we owe our excellent health to them.

Firstly, I would like to say an enormous thank you to Julia Forjanic Klapproth (Julia FK) who was President until a few weeks ago. Julia FK's involvement with EMWA started 11 years ago when she became Membership Officer. Since then she has been Vice President twice and President twice! During her most recent period of office, Julia FK instigated the idea of conference themes. She has run conferences with the themes of 'medical communications', 'medical translations' and 'regulatory writing', and each time she put together a fantastic line up of plenary talks, seminars, and discussion panels. There's something about Julia FK: people just can't say 'no' to her! (I know that for a fact as I ended up as EMWA Vice President even though

my husband and colleagues told me to phone her and just say 'no'!) Julia FK is truly one of the most brilliant and dynamic women I have ever met and I was very lucky to have her train me for my present role.

Three other members of the EC recently stepped down and all deserve an enormous show of hands for their dedication to EMWA. Julia Cooper (Julia C) was on the EC for 12 consecutive years as Education Officer, Vice President, President, Past President, and most recently Honorary Secretary; last year she oversaw the transition from our previous head office in Switzerland to our new head office in the UK. Wendy Kingdom was on the EC for 6 years as Education Officer and then Treasurer. EMWA's finances are under control largely thanks to the great care that Wendy has taken of our money! Under her guidance, EMWA has invested its funds wisely and has built up a reserve to cover the possibility of having to cancel a conference at the last minute (due to Mexican flu for example!) Finally, Kari Skinningsrud was PR Officer for 4 years helping to spread the good name of EMWA far and wide by attending conferences and designing promotional materials including a very attractive brochure and a useful career pack for would-be medical writers. Thank you to them all and I hope they can now have a good (well-earned) rest!

There's one more person that I really need to mention here, and that's Stephen de Looze. I am delighted to announce that Stephen was awarded a Nick Thompson Fellowship at the banquet in Ljubljana. Stephen joined the EMWA Professional Development Committee (EPDC) in 2000 and was Education Officer from 2001 to 2003, expanding the EMWA Professional Development Programme (EPDP) from about a dozen workshops to over forty. He subsequently developed, with other EPDC members, the advanced curriculum (launched in 2005). During his second term as Education Officer (2007-date), Stephen has further expanded and improved the education programme (we now have around 80 EPDP workshops) and has participated very actively in many other aspects of running EMWA. I am delighted that Stephen has agreed to continue in the role of Education Officer for the next two years and I warmly congratulate him on his well-deserved award.

I'm happy to say that the Ljubljana conference was a great success and again I would like to thank everyone who participated as a workshop or seminar leader, plenary speaker, or panellist. All of these people give their time on an entirely voluntary basis, they are not paid, and the conferences

Message from the President

could not exist without them. I would also like to mention that our new head office provider, MCI, did an excellent job of running the conference and I have received many compliments about how professionally it was handled.

With all those people to thank, I haven't got much space left to tell you about the programme for this year, so I'll have to save some for the next issue! Our next conferences will be in Frankfurt (12-14 November 2009), Lisbon (May 2010) and Nice (November 2010). We also plan to run our third joint symposium with the Institute of Clinical Research (ICR) in February 2010. The theme of the Lisbon conference will be 'Medical Writing in an Electronic Era' and we are currently looking for plenary speakers, seminar leaders, and discussion panel topics—so please do contact

me if you have any suggestions. We are also launching a new idea of a 'call for brief presentations' for the Lisbon conference: the aim is to increase the opportunities for EMWA members to present and share their knowledge and opinions with others.

Well that's all for my first President's Message. It was easier than I expected (rather like abstract writing—the hardest thing is keeping the word count below the limit)! I wish you all a wonderful summer and I look forward to catching up with you again in a few months time.

Helen Baldwin

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What's news at EMWA?

The EMWA Spring Conference, Ljubljana, 2009

EMWA's 28th Conference took place from 26-30 May in Ljubljana, the capital of Slovenia. 264 EMWA members registered for the conference. There were over 60 sessions, primarily workshops for credit in the EMWA Professional Development Programme but including 4 plenary lectures, a keynote lecture and discussion forums. Although the theme of the conference was regulatory writing a remarkable diversity of topics of interest to medical writers was on offer and the conference clearly achieved the goal of having 'something for everybody'—medical writers working in pharmaceutical companies, medical communications, clinical research organisations, academia, government institutions, hospitals and last but certainly not least, freelancers. Opportunities for informal discussion were provided by the lunchtime discussion tables and, of course, the social events provided great opportunities for networking.

The Annual General Meeting (AGM)

Over 90 members registered for the AGM. Ziga Arh, *TWS's* publisher who is based in Ljubljana, gave an excellent presentation in which he traced changes in the journal's development since 2002 when he took over the publication process. Not only have the number of issues increased from 3 to 4 per year but the number of pages has increased from 32 to 70. Added to this the change from the single column 'letter' design to a 2-column format doubled the words per page. Ziga explained the production process, including examples of the designer's work on tables and images and the preparation and checking of galley proofs, as well as the distribution process. Finally he considered the potential for further developments: gathering boxes under section headings, reintroduction of quotation boxes, a bound journal with thinner paper, improved photographic and illustration quality, moving the list of contents from the



Laurence Auffret Laura Hollyhead Gillian Pritchard Andrea Palluch

back cover to release this space for conference announcements and adverts and more.

This conference was the first to be run by our new head office MCI and they provided each of us at the AGM with 2 voting cards: a 'Yes' card with a green background and a 'No' card with a red background. That red card was ever so tempting, but the opportunity to use it never arose. The motions that were passed were:

- to approve the annual accounts for 2008, together with the budget and membership fee for 2010
- to release the EC, i.e. to sign off on the activities of the current EC since the last AGM
- to allow EMWA to re-activate the UK registered company and a second motion to close down in Switzerland
 - to allow the EC to invite current members of the Swiss entity for admission to membership of the UK entity
 - to close down Swiss EMWA subject to, and conditional upon admission to membership to the UK entity by a majority of the current membership of the Swiss organisation.

Finally EC officers were elected for all open vacancies. Helen Baldwin moves from the position of Vice President to President, Stephen de Looze continues in the position of Education Officer. Shanida Nataraja remains as Web Manager and I remain as Journal Editor. These last two positions are non-elected and appointed by the EC. The new EC members are Vice President: Laurence Auffret, Treasurer: Gillian Pritchard, Honorary Secretary: Laura Hollyhead, Public Relations Officer: Andrea Palluch. ■

Elise Langdon-Neuner
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>>> What's news at EMWA?

Plenary and keynote lectures

The plenary lecture titled 'Fraud in medical research and scientific communication' presented by Frank Wells will be the subject of an article by Catherine Mary to be published in the September issue of *TWS*.

Plenary Lecture: Regulation on the Publication of Clinical Trials

Presented by Kathy B. Thomas-Urban

The latest status of clinical trial disclosure was summarized. This fast developing regulatory field affects disclosure of information on clinical trials in a public domain (Internet) with prospective registration for *new or ongoing* clinical trials and *retrospective disclosure of the results* for *completed* clinical trials, and has global implications for all sponsors of clinical trials.

Stringent demands for increased public transparency of clinical trials came from the International Committee of Medical Editors (ICMJE), the WHO, The World Medical Association, governments and drug regulatory authorities in many countries around the world, as well as from the patient groups and general public.

Requirements for Clinical Trial Disclosure differ between countries. *Laws in force* have been established by the European Parliament for all 27 countries of the European

Union (EU); some of parts of the laws apply to the European Economic Area (Iceland, Lichtenstein, Norway). *National laws* exist in Argentina, Canada, Croatia, Czech Republic, France, India, Israel, Hong Kong, South Africa, Taiwan, and USA. *National guidelines*, set up by the health authorities or ethics committees on this topic exist in: Australia, China, Germany, Iran, Japan, The Netherlands, New Zealand, and Spain. In some countries registers are in the national language in addition to English; some allow a crosslink from an international register to avoid duplication of entries. The most widely used database for clinical trials is the register www.ClinicalTrials.gov administered by the National Library of Medicine, USA. It contains information based on the study protocol on new and ongoing studies as well as results of completed studies is the register www.ClinicalTrials.gov administered by the National Library of Medicine, USA. A global search for information on clinical studies can be done through search portals such as the <http://www.who.int/ictrp/en/>, administered by ICTRP (International Clinical Trial Registry, at the WHO).

The applicable law for clinical studies with drugs, biologics, and medical devices in the USA or studies that are part of a regulatory FDA application is the 'FDAAA of 2007' (Law 110-85, Section 801 (Title VIII)). It mandates the reg-

EUROPEAN ASSOCIATION OF SCIENCE EDITORS
Tenth General Assembly and Conference
Second Circular, Programme and Registration Information

Integrity in Science Communication

At the Palazzo dei Congressi, Pisa, Italy, 16 – 19 September 2009

Plenary sessions

- Opening lecture by Professors Lucia Tomasi Tongiorgi & Romano Coppini
- Keynote lecture by Professor Ele Ferrannini
- Physical Integrity
- Moral Integrity
- Editorial Independence and Responsibilities

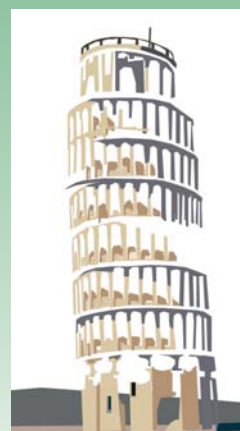
Parallel sessions

- Publication of full datasets
- Cultural issues relating to non-English journals
- Authorship
- Misconduct in science communication
- University Press Challenge
- Cultural integrity of journal guidelines and their translation
- The role of editors and journals in fostering responsible conduct of research
- Promoting the public perception of science through clear communication

Optional Workshop

Managing a Journal Editorial Office

See www.ease.org.uk for details



What's news at EMWA?



photo: Crispin Hodges

istration of **all** applicable clinical trials (Phase II to IV) on the database www.ClinicalTrials.gov, within 21 days of first patient enrolment and regular maintenance of the enrolment status and the trial completion. Results of the trial must be shown on the same database. This applies to completed trials (Phase II to IV), performed with **FDA-approved products**. The timing for results disclosure depends on the stage of product development, i.e. for trials with an *approved product* studied in an *approved clinical indication*, the timeline is 12 months from the completion of the primary parameter (specified in the trial registration); for *unapproved products*, the timeline is 30 days after product approval; the disclosure of results applies to applicable clinical trials (dating back to trials that were ongoing in or after September 2007). The format for registration and results disclosure of clinical trials must follow the information fields specified by the database on www.ClinicalTrials.gov. The requirements of the FDAAA of 2007 are being introduced gradually over 3 years and should be completed by the end of 2010: •registry information for new and ongoing trials is generally required as of December 2007, •basic results disclosure of completed studies is required as of September 2008, •adverse events reporting will be required from September 2009, •lay summaries of the trials result, by the end of 2010, and •potential expansion of the law to disclose clinical trial information for **unapproved products** is



photo: Crispin Hodges

expected by September 2010. It is the trial sponsor who is obliged to disclose the information; most FDA regulatory drug applications require a proof of compliance; the law specifies penalties for non-compliance.

Two regulations by the European Commission apply for clinical trials in the EU. They deal separately with the clinical studies involving children [*'Paediatric Regulation'* (EU) Article 41 of Regulation (EC) 1901/2006]; and those with adults [*'All clinical trials'* Article 57(2) of Regulation (EC) 726/2004]. In contrast to the situation in the USA, the clinical trial information in the EU will be released automatically to the public by EMEA (European Medicines Agency) from its database EudraCT via the EudraPharm. The released information will be based on the data supplied by the sponsors to EudraCT as part of the clinical trial application and as part of the results reporting. The requirements apply to **all** products (**approved and unapproved**) studied in Phase I to IV clinical trials with children, but Phase II to IV for clinical trials with adults. For results disclosure, the proposed format must follow the Synopsis used for Clinical Study Reports (ICH E3 guideline). After completing the clinical trial, the timelines for results disclosure are 6 months for trials with children and 12 months for trials with adults. Both regulations are in force already, although the technical aspects of the publicly available information are still under construction. The planned release of the information to the public for registration is expected by the end of 2009 and for disclosure of results by the middle of 2010. ■

Kathy B. Thomas-Urban

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Keynote Lecture: Harmonization of the Clinical Parts of the Common Technical Document (CTD) Dossier in the EU & US: Is it Possible?

Presented by Craig McCarthy and Linda Tollefson

Although ICH guidelines were introduced to achieve harmonization of the CTD, a single harmonized dossier is often impeded by different regulatory requirements in the US and in Europe. Craig McCarthy (President and Fellow of The Organization for Professionals in Regulatory Affairs [TOPRA]) pointed out some of the major differences between a US and a European CTD, including the requirement of 2 placebo-controlled studies in the US vs. a single active comparator study in Europe, or the way that clinical data are reviewed 'bottom-up' by the FDA vs. 'top-down' by the EMEA. He concluded that unless the different agencies come up with harmonized requirements, the only way to achieve a reasonably harmonized CTD dossier is to obtain scientific advice from both the US and European authorities. He then handed over to representatives from the FDA (Linda Tollefson, Director of the FDA Europe Regional Office) and the EMEA (Segundo Mariz, Medical Assessor at the Medicines and Healthproducts Regulatory Agency [MHRA]) with the question if and when we can expect harmonization of the clinical parts of

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>>> **What's news at EMWA?**

the CTD. Both were not able to give a clear answer to this question. They both presented an overview of their agency requirements and processes, and emphasized that scientific advice meetings are absolutely essential to a successful clinical development programme and should be used proactively and wisely. Linda emphasized that 70% of major deficiencies of a CTD can be identified at pre-submission meetings. Furthermore, they pointed out that relevant guidelines issued by the agencies are often not considered appropriately. During the panel discussion, the fundamental question if documents can get rejected by the agencies if they are badly written was answered by Linda with a clear yes. On the other hand, Segundo said he does turn directly to the study reports and source data if he gets a clinical overview that is not understandable, but that this is usually a disadvantage to the applicant since it is likely he will oversee important messages that the sponsor may want to get across. The resounding opinion of all the panel members was that sponsors should seek more contact with the authorities, both FDA and EMEA, to try and clarify as many things as possible before submissions. ■

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Plenary Lecture: The FDA Takes Up Residence in Brussels—There Goes the Neighbourhood!

Presented by Linda Tollefson

The FDA is coming to Brussels. The question you may be asking is, why? On Thursday morning at the conference in Ljubljana, Linda Tollefson, the director of the new Brussels office, gave an enlightening plenary lecture to answer just that question. The FDA has been charged by the US congress to proactively find ways to harmonize itself in a global world. To do this, the FDA has opened offices around the world to develop and nurture relationships with other regulatory agencies. The hope is that by working together, the agencies can save time and resources by not having to duplicate efforts. For example, the auditing of drug production facilities, clinical study sites and organisations involved in the development of new medicines, devices and even cosmetics could one day be per-

formed by one agency and the report produced accepted by others. Similarly, there is a goal to find ways of avoiding redundancies in the drug approval process in different regions and thereby speeding up getting new drugs to the market. One way they plan to do this is by having joint scientific discussions with EMEA when pharmaceutical companies ask for scientific advice during their drug development programmes. While Linda admitted that this is no guarantee that both agencies will provide similar advice, it will hopefully make both sides aware of other perspectives, and in some way aid the general consolidation of ideas. It is certainly an interesting idea for the FDA to open an office in Brussels and I am interested to see how it will impact on the attempt to harmonise the global drug approval process. The question I have now, is when EMEA will open an office in Washington... ■

Julia Forjanic Klapproth

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Plenary Lecture: The Precautionary Principle: An approach to Risk Management

Approach by Stuart Woods

The Precautionary Principle is a principle that has been in existence for millennia. The expression ‘better to be safe than sorry’ captures the concept very well. In the medical field Hippocrates embraced it when he advised “first do no harm”.

In more recent years the Precautionary Principle has been applied as a regulatory principle, most obviously with respect to the protection of the environment. There have been many definitions—and interpretations—of the principle, but all relate to the management of risk in situations of scientific uncertainty, and adopt the position that a lack of scientific certainty is not a justification for regulatory inaction.

Today the Precautionary Principle is a compulsory principle of European law. Although the law only mentions it in relation to environmental issues, according to the European Commission it may be applied to all risk regulation activities within the European Union.

Two key factors have perhaps combined to lead regulators to extend the scope of application of the principle beyond the environment: increasing consumer access to information (especially via the internet) and increasing aversion to risk.

Regulators face a dilemma. In today's world the level of media/consumer attention directed towards a particular topic may be such as to oblige that they take decisions before scientific investigations are completed. Thus, in the words of the Commission, the application of the Precautionary Principle is a “political decision exercised in conditions of scientific uncertainty” that “reflects the need to take action in the face of a potentially serious risk without awaiting the results of scientific research”.

The finding, in the mid 1990s, that the agent of bovine spongiform encephalopathy (BSE, mad cow disease) was transmissible to, and caused a spongiform encephalopathy in, man was perhaps the first stimulus for the application of



photo: Crispin Hodges

What's news at EMWA?

the principle in the pharmaceutical arena. Bovine-derived materials are not only eaten, they are widely used by many industries, including the pharmaceutical industry.

Spongiform encephalopathies are invariably fatal neurological diseases. The diseases have long incubation periods. The agents that cause them are difficult to inactivate. The infectious dose may be small and the pathogenesis of the diseases is (still) not fully elucidated. In addition, the geographical distribution of BSE in the 1990s was uncertain and the level of public concern was very high—a classic scenario for the application of the principle.

Regulators and the pharmaceutical industry worked very closely together to address possible BSE-associated risks and the controls that have been put in place are universally supported and applied. Reassuringly, scientific findings to date have shown them to be appropriate.

Could it be that a legacy of BSE—an increased focus on precaution and the principle of precaution—remains?

In 1999, the European Council of Ministers urged the European Commission “to be in the future even more determined to be guided by the Precautionary Principle in preparing proposals for legislation”. Did the Council have BSE in mind? I suspect that they did.

Current pharmaceutical legislation does not specifically mention the Precautionary Principle, but recently issued draft regulatory guidance relating to vaccine products does. This draft guidance advises that there are perceived concerns in the public arena that relate to vaccine safety and that these must be addressed. It links a precautionary approach to a need for greatly increased emphasis on proactive and ongoing post-licensure regulatory management, including safety and other studies, throughout the life-cycle of the product.

Will this life-cycle approach extend to other therapeutic areas? In my view, this is inevitable. Regulators are obliged to react to the increasing risk aversion of the consumer and to media attention. There have been a number of high profile therapeutic product withdrawals as a result of safety concerns. A recent publication authored by senior European regulators noted that “the point of approval should not be the last call for major regulatory action” and that “a sharp increase” is to be expected in post-marketing clinical research activities” as part of “life cycle regulatory management”.

Will it happen? I am sure of it. Consumers, the media and consumer concerns are not going to go away.

Will the Precautionary Principle have played a role in provoking this change of emphasis? I believe so.

Will it impact medical writers in their work? I think that it most definitely will. Some, perhaps many, of the studies that are required will be of a type that is unfamiliar to us. The players that are likely to be implicated, together with companies, are going to be different from those that have conventionally supported product development—for exam-

ple health authorities, authority advisers and health care providers. It is probable that different skill sets will have to be developed.

It will pay us all to be prepared! ■

Stuart Woods

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Lunchtime discussion tables

Lunchtime discussion tables were held on the Thursday and Friday. In addition to the reports below, Phil Laventhal has written an article in the Out on Our Own freelance section about the discussion at the table with the theme ‘Freelance or employee: Which is better?’



photo: Crispin Hodges

Frames of reference; regulatory versus marketing messages

Discussion leader: Leanne Walsh

This round table was intended to encourage medical writers to exchange their experiences and share advice on being caught between the needs of regulatory departments and the desires of marketing departments when writing documents. The discussion table was held twice and the participants had diverse personal experience with the topic. We animatedly discussed the difficulties some of us have experienced in final decision making responsibility, and tactful teamwork;

- we agreed that all statements need to be based on sound scientific data
- one group concluded that in fact non-scientifically sound statements are more frequently made by external experts rather than from within pharmaceutical companies
- the other group concluded that marketing departments in pharmaceutical companies may push for overstatement

It seems that a lot of medical writers feel caught between the scientific and marketing forces of the pharmaceutical messaging world but the round table discussion produced some good tips for resolving conflicts when confronted with difficult situations as well as the recognition that great support can be offered amongst medical writers on this topic.

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>>> **What's news at EMWA?****Medical writers and pandemic influenza***Discussion leader: Robert Kahn*

This discussion group considered the possibility of an influenza pandemic and what we as medical writers could do in practice. At present, the situation with such mild, but widespread, influenza is not too alarming. However, the key question is how the virus will mutate when the H1N1 virus with its high transmissibility links up with the H5N1 virus with its high virulence, perhaps this winter in China. As medical writers we felt a responsibility to communicate, both with other medical writers and with the public. It was the failure to communicate during the 1918-1919 pandemic that led to a breakdown in trust between government and the public, as John Barry pointed out in his open-access 21 May article in *Nature*. The reality now was that viruses in any country were a threat to the rest of the world, as David Brooks wrote in "Globalism goes viral," in *The New York Times* of 28 April, on the web at: www.nytimes.com/2009/04/28/opinion/28brooks.html. However, such threats needed to be faced locally, with small groups of people committed to better hygiene, social distancing, and hopefully antivirals, and later vaccines. The importance of dealing with the media was considered, as set out by Debra E. Blakely in her book, *Mass mediated Disease: A Case Study Analysis of Three Flu Pandemics and Public Health Policy* (Lexington Books, Plymouth, UK, 2007). Interest was expressed in forming a group of medical writers who communicated regularly with each other by e-mail, and possibly later through a website. Those interested in being part of such a group, either as contributors or as readers, were asked to contact Robert Kahn at: rs_kahn@hotmail.com.

Medical writing management challenges*Discussion leader: Kari Skinningsrud*

4-8 people participated in the lunch-table discussions at each session on Thursday and Friday. We discussed how the formal role of project manager is usually given to others rather than to medical writers (MWs), but that MWs have to take on a manager's role anyway to be able to complete the work they are expected to do within a given timeline. It was mentioned that MWs need to educate their customers—including other professional groups within companies—and be able to explain how their work can be split into packages with time allocated to each one. This makes it easier to present arguments for delays. Causes for delay should be recorded and systematised so the last person in the chain (the MW) is not automatically identified as the problem, but this needs to be done wisely so it doesn't all reduce to distributing blame. Medical writers need to develop management skills and accept that this part of the job will often not be acknowledged, it is just an inherent and unavoidable part of any MW's job. Multidisciplinary, multicultural teams are typical work situations for MWs.

It's one thing to communicate exactly what our job implies, but another to do it to people who often know very little about our job and qualifications, and are even situated in other countries with quite different cultures.

Online social networks—kick-starting a freelance career*Discussion leaders: Laurence Auffret, Joeyn Mieke Flauaus and Laura Russell*

Marketing yourself online is not an easy task, and around this lunch table, experts and newer users were at hand to discuss how useful social-networking tools can be and share their experience and thoughts on how to best use them.

This was a very stimulating and animated discussion that reached its objectives of both introducing the topic and consolidating the skills and confidence of online-network users. The issues involving practicality, usage and effective networking were discussed, and queries ranging from "Which online network shall I use?" to "What is the best way to attract attention?" served as a basis to cover many aspects of online networking. We examined the specific questions raised by participants in greater detail, and our various levels of experience allowed us a thorough examination of each issue. Thanks to the way delegates enthusiastically engaged with the topic, regardless of their experience, we managed to cover a great deal of ground within a mere 45 minutes. The discussion will be continuing electronically, on the EMWA discussion forum and via email, and several participants have already reported about steps they took after the lunch group met.

More details about our collective progress, concerns and experience are currently being compiled for an article which will appear in the next *TWS*.

EMWA Book Discussion: Lucky Man by Michael J Fox,*Discussion leaders: Wendy Kingdom and Alison McIntosh*

This year the book we chose to read and discuss at the conference was *Lucky Man* by Michael J Fox, however, due to a clash in timings, and other EMWA commitments no lunch time discussions were able to take place. Apologies then, to those who read the book but were unable to join in discussions. Hopefully the following review of the book will help allay any disappointment.

Fans of *Back to the Future* will recognise Michael J Fox as Marty McFly, cheeky young chap and time traveller. Born in Canada, Michael became famous in the USA playing the part of Alex P. Keaton in the sitcom *Family Ties*. He has won an impressive list of awards and has starred in a host of movies and television productions.

In 1991, when Michael was just 30 years old and at the height of his career, he was diagnosed with Parkinson's disease. He did not disclose his condition to the public until 1998.

The first half of *Lucky Man* is an entertaining description of Michael's early years in Canada, followed by an honest and insightful look at his life in Hollywood. It is interest-

What's news at EMWA?



Stephen de Looze, who received the Nick Thompson Award (centre).
Kathy Thomas-Urban (left) and Beata Wieseler (right)

ing to read about the living conditions of the actors who are 'resting', the people who help celebrities to spend their money, and the uninhibited living of the rich. The "I'm famous, you're famous" club is, apparently, a gathering of people who know each other, not as we mortals might understand friendship, but in the sense that they recognise each other because they are all famous and they know what it's like to be known by everyone else.

Michael was diagnosed with Parkinson's disease about a year after he first noticed a tremor in one finger. For a long time, he tried to pretend that it wasn't happening. The section of the book in which Michael describes his period of denial about the disease is heartbreaking. He turned to alcohol and spent hours in the bath with the lights turned off. He hit rock bottom when he was so drunk that he missed an important appointment and his wife, Tracy Pollen, said to him, "Is this what you want? *This* is what you want to be?" This shocked him into recognising that he had to face up to his condition and learn to live with it otherwise he could lose his wife and children.

As with many autobiographies, the writing does not always flow well. In particular, it is difficult to follow the chronology in the first half of the book. However, the descriptions of what it is like to live with the progressive symptoms of Parkinson's disease are interesting. Michael has tried all of the drugs that are available and he tells us about the pros and cons of each. He has even had brain surgery whilst being fully conscious.

The *Lucky Man* of the title is how Michael sees himself because he has the love and support of his family. Ultimately, this is a moving story by a man who has had to face an abrupt change in his expectations of life. Michael now uses his celebrity status to raise awareness of Parkinson's disease and to raise money for research.

As an addendum, the second instalment of Michael's autobiography has been released recently and is entitled *Always looking up. The Adventures of an Incurable Optimist*. In this new book, he describes the last 10 years

of his life, when he has been working out how to have a fulfilled life whilst living, coping and struggling with what he describes as "the ravages of Parkinson's disease."

References:

1. *Lucky Man: A Memoir*. Ebury Press; New edition edition (2 Jan 2003). ISBN: 978-0091885670. 304 pages.
2. *Always Looking Up*. Ebury Press (16 April 2009). ISBN:978-0091922641. 288 pages.

Social programme

The social programme included walking tours, a boat trip, wine tasting and dinners in typical Slovenian restaurants. The banquet was held at the conference hotel, The Grand Union, in a beautiful room that has seen former days as a cinema. At the banquet each of the Executive Committee members who stood down at the AGM including Julia Cooper (Honorary Secretary), Wendy Kingdom (Treasurer), Kari Skinningsrud (Public Relations Officer) received well-deserved thanks from the new president. Stephen de Looze received The Nick Thompson Award in acknowledgement for all his hard work for EMWA over many years.



The highlight of the other social events was a trip to the Postojna cave.

Spelunking for dumplings

by Geoff Hall, with Lisa Chamberlain James doing the walking

"... and if we're lucky we might see a human fish." Now, I've been on enough tour buses and complimentary conference airport transfers to be very wary of the information imparted by the guides. Try listening to what one of these people has to say about your home city if you doubt that a lot of this guff is inaccurate, based on legend rather than history or simply designed to deceive mischievously.

We were on our way to the Postojna cave—two busloads of medical writers and accompanying persons taking advantage of the Ljubljana conference social programme. When our courier raised the issue of the human fish, my incredulity level peaked.

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>>> What's news at EMWA?



photo: Rainer Bishoff

Still, he added a few bits of supportive detail, none of which, however, was too convincing.

The bus ride from the city would take less than an hour and, as we turned off the highway, I was surprised to see that, after such a short journey we were only a few tens of kilometres from Trieste in Italy. Slovenia is only a small country. The Postojna Cave (pronounced poshtoyna) must be nearly as big. The whole system comprises over 20km of underground caves,

And what caves.

One of Slovenia's most popular tourist attractions today, the various people who have governed this part of the world over the last couple of centuries have all realised and enhanced this potential. Though the caves had been known since at least the 1600s, the discovery of new networks of caverns led to them being opened to the public in 1819. The authorities installed electric lighting in 1884 providing a brilliant spectacle for millions of visitors since. The Postojna cave had 'street lighting' before the capital Ljubljana.

Those of us who are not quite as agile as we would wish were delighted to find that our 5 ½-km journey into the cave was not to be on foot. A 4-km train ride into the cave system, through cathedral-like caverns, concussion-threatening tunnels and dramatic drip formations of rock, took us to the start of the subterranean trek.

The rails date from 1872. In those days, muscles of the cave guides provided the power. These days electricity does the job, providing easy access to the longest publicly accessible depth of any cave system in the world. An abiding memory of this conference was of immediate past-president Julia borrowing various items of ill-matched clothing in order to keep vaguely warm. This was certainly needed in the cave. The temperature is a constant 10°C and Julia became almost certainly the first woman to tour the caves in a Marylebone Cricket Club member's sweater.

The official guide says "Well kept paths for tourists comprise the greater part of Postojna Cave, making it a 'horizontal' cave. Thus a visit to the cave does not present any difficulties for most visitors."

I've no idea whether that is so or not. I, together with one of our plenary speakers, Dr Frank Wells, opted to stay on the train. Although this followed the same track as the way in, the experience was very different. Just the two of us in silence taking in the spectacle.

Lisa Chamberlain James takes up the story of the caves on foot:

I have to admit to a feeling of grave foreboding when faced with the suggested 'head-to-foot hooded blanket cave attire for hire' on a model at the entrance to the caves (I was sensibly dressed in a summer frock with no sleeves...). However, after the wind chill on our thoroughly enjoyable (although slightly white-knuckle) train ride, we alighted to a positively balmy atmosphere and dutifully set off after our guide up a rather steep incline.

At this point, the group began to fracture into the seriously well equipped and fit (at the front), the rather less well equipped and/or fit (in the middle), and the not at all fit, and/or well equipped, and/or just talking too much (at the back—of which I was a firm member). What was very noticeable was the unanimous 'oo-ing' and 'ahhh-ing' that emanated from all three groups (think firework night but without the loud bangs).

It is hard to describe the sheer scale and beauty of the caves. Every corner revealed a different colour or formation, and we were carefully led through the different 'galleries' by our very informative and patient guide, who explained the formation of the stalagmites and stalactites, their different colours, and the incredible length of time it takes for them to form (one variety takes 100 years to grow 1 mm). We even passed through the 'spaghetti gallery'—thousands of stalactites on the ceilings all looking like elongated macaroni, and were introduced to 'the diamond'—the emblem of the caves and a beautiful, pure white stalagmite.

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The tour ended in the 'concert hall'—a truly amazing space with an echo that lasts around 6 seconds. I must confess to being slightly disconcerted (if you'll excuse the pun) by the thought of loud noises echoing around caves full of lethal-looking (albeit beautiful) stalactites...but then, I can think of worse ways to go than being impaled by a glittering shard of spaghetti-shaped rock that's taken thousands of years to form!

Admittedly, I was a little torn when I booked the cave trip. There were plenty of other exciting trips on offer that night, and a cold, damp, tramp around underground is not my usual choice of pastime. However, I'm SO glad that I was persuaded to go—I saw sights that I will never forget, and that a camera will never be able to reproduce faithfully. It was a truly special, almost magical place, and I would urge anyone to go back and see it (but maybe give the summer frock a miss....).

Back at the bar (sorry) restaurant

Frank Wells and I spent a convivial hour or so reminiscing about old times and enjoying an excellent Slovenian chardonnay before the rest of the group rejoined us for dinner. The package had included dinner in the caves restaurant and I was expecting something pretty ordinary from a tourist attraction diner. How wrong can you be? A beautiful room where we were served a delightful starter with a beautifully tender steak in a hunter's sauce for main course. Unfortunately, like so much grub in central Europe it was accompanied by dense heavy, but pretty looking dumplings. Then an apple strudel that impressed even the non-pudding-eaters.

A great trip. If you have a chance to go—don't miss it.

Oh and the human fish? Well it's true. A cave-dwelling blind creature completely adapted to life in the dark—*Proteus anguinus*. It's also known as the olm or the cave salamander. Part of the tour through the caves used to include a pool with some human fish in it. These have been removed due to the effect flashes from visiting tourists' cameras had on the sensitive human-like (hence the name) skin of the creatures. The official guide tells me that "To see one now, you must visit the Vivarium outside the cave." Missed that. We were in the bar. ■



Photograph taken in South Africa by Maria Wendt

Call for Abstracts for Brief Presentations

**30th EMWA conference:
11-15 May 2010, Lisbon**

For next year's spring conference, EMWA has decided to try out a new idea of opening the floor to all participants who would like to give a brief presentation on any interesting topic related to medical writing. The format will be 10 minute slide presentations followed by 10 minutes for questions/discussion. The topic should be of interest to other members and may include: hot topics, controversial areas for discussion, new guidelines or technology, etc.

If you are an EMWA member, you should have received an email inviting you to submit an abstract for a brief presentation on the appropriate form (maximum 200 words). You can also download the form from our website or e-mail head office for a copy (info@emwa.org). The deadline for submitting abstracts is 31st July 2009.

Once all abstracts have been received, a subcommittee will review them, and the most interesting ones will be selected to be presented at the 30th EMWA conference in Lisbon next May.

This is your opportunity to stand up and tell your colleagues about an aspect of medical writing that you feel strongly about. We're looking forward to hearing from you!

Helen Baldwin

EMWA President

Themes of upcoming issues of TWS

The September issue of *TWS*, which will be guest edited by Adam Jacobs (ajacobs@dianthus.co.uk), will have a statistics theme. December's issue will have a medical communications theme and will be guest edited by Ursula Schoenberg (u.schoenberg@t-online.de). Articles are also invited on preclinical regulatory topics. Future issues featuring business and electronics for medical writers are also planned.

Articles (up to 2500 words) and short reports/boxes (up to 1000 words) on these topics or any topics of interest to medical writers, medical translators, or trainers in the field are very welcome.

Elise Langdon-Neuner

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