The Write Stuff

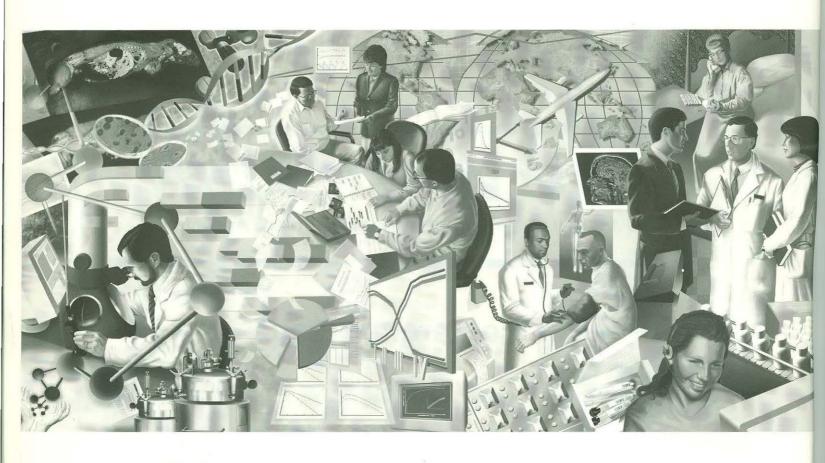
The Journal of the European Medical Writers Association

Postconference Issue

Featuring:

- "You had to be there! "Eighth Annual Meeting in Copenhagen Fiona Swain
- The Strange World of Adverse Events Julia Cooper
- The Freelance Contract Cathryn D Evans
- The Non-natives are Restless: a Call for Dialogue Hilde Joosen
- The Patient Information Sheet Judi Proctor





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Shaping Solutions

Postconference Issue (Spring) Vol 8, No. 2

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"It was the best of times, it was the " well, actually it was just a great time for everyone. Time to renew friendships and contacts, learn the latest techniques of our art, discover how many of us have changed companies or gone freelance, find out if the beer in Copenhagen compares to that of Madrid and Edinburgh, etc. Too bad if you missed it, but next year in Dublin promises to be even better see ya there!	
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Collected by Julia Cooper Ever since Viagra was discovered by virtue of its adverse events, clinical researchers have been paying more attention to these events. Try and imagine some of the interesting new "lifestyle" products which would result from drugs that cause some of these, collected from years of clinical research and chanced upon by Julia Cooper. [INT]	
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Cathryn D Evans An experienced freelancer offers a sample contract representative of those she uses. The sample given is for projects at a flat rate or on an hourly consultation basis for pharmaceutical or other companies. [reprinted from the AMWA Journal with permission].	
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Hilde Joosen Many people tend to associate medical writing with native English speakers, since most medical texts, regardless of the country of origin, are written in English. The reality in Europe, however, is otherwise and this will probably increase as the field of medical writing expands and becomes more established. [INT]	
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http://www.emwa.org

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued quarterly and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

Articles or ideas should be submitted to the editor-in-chief:

Barry Drees

Tel: (+49) 69 305 3834 Fax: (+49) 69 305 80070

e-mail: barry.drees@hmrag.com

Subscriptions:

Subscriptions are included in EMWA memberships. Non-members can subscribe at an annual rate of:

- £20 within Europe
- £30 outside Europe

Back Issues:

Subject to availability, previous issues of the EMWA newsletter can be obtained for the cost of mailing by contacting Phillipa Clow at the EMWA secretariat.

Advertising Rates:

Corporate

Full page £200Half page £100Quarter page £50

Private

Freelance members only

Full page £100Half page £50Quarter page £25

(all rates in pounds sterling)

Instructions for Contributors:

- The Write Stuff typically publishes articles of 500 - 1500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board.
 Any changes to a contribution will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone/fax numbers and e-mail address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted electronically on computer disc or by e-mail as an MS Word file using Arial font (or equivalent), 11-point, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV-style).

Behind the press...

Editor-in-Chief Barry Drees

Artistic Director

Julia Forjanic Klapproth

Copy Editing
Chris Priestley
Judi Proctor

Meetings of Interest Sarah Heritage

From the Literature Liz Wager



The Editor's Red Pencil

by Barry Drees

Greetings fellow members,

This issue is the fourth since the format change and represents the end of the first full year of publication of *The Write Stuff* (TWS). I am very pleased to be able to report to you all that we were able to achieve our very ambitious goal of putting out a publication four times a year and I hope you'll agree with me that with the possible exception of some continuing, irritating printing problems, we now have a quality journal we can all be proud of. Although I'm the editor, I couldn't have done it without the help of the other members of the Editorial Board, the contributing authors, and all those who've written in with comments, suggestions or encouragement — thank you.

As I look back on the birth of the new EMWA journal, all I can say is, WOW, have I learned more than I ever thought I'd want to about printing, publishing, editing and proof-reading. There have been more than a few hiccups in the whole process, but all in all, I think it has functioned fairly well and I'm happy to see things are settling down

and getting more routine with this issue. I don't want to suggest, however, that we can go over to cruise control or that there isn't still big room for improvement. I have a number of ideas, which I hope to implement this year for making things even better.

WOW, have I learned more than I ever thought I'd want to about printing, publishing, editing and proof-reading

Well, say what you want, but a different layout style every issue is never boring! Many of you may be a bit disappointed at the reduction in colour in this issue, I know I am. However, the sad fact is (and one of the many things I learned about printing this year) that using different colour text on each page was slowing down printing considerably while adding substantially to the cost. When I initially planned TWS, the printer told me that each additional colour added to the price. What I didn't realise was that changing the text on each page that needed to be done in the second colour was similar to using a different colour on each page, since a separate plate had to be prepared and a print run performed for each page where the coloured parts were different. This made me curious, and sure enough, most publications that are not full-colour restrict the use of colour to the front and back covers (check out the AMWA Journal, for example, which is strictly black and white). Thus, in order to be more timely and economical, I've restricted the green on the inside to the header and footers. I really don't think we've lost too much, and it will streamline printing.

The Editor's Red Pencil

Nothing warms the heart of an editor more than receiving a response from a reader. Therefore, I can't think of any better way to celebrate the first year of the new format than to be able to share with you some of the correspondence we have received. As I noted in the last issue, alternative medicine is both a current and controversial topic and sure enough, it generated our first real correspondence. Well, OK, we have received lots of letters from you saying how much you like the new format or pointing out yet another printing slip-up (Ugh), but this is the first time that we received something that actually addresses an issue in one of our articles. Naturally I'm thrilled to see that someone is actually reading and thinking about the things we print (rather than just hunting for errors) and I'm hopeful that we'll receive many more such responses in the future; maybe we can even generate a few long-running exchanges! We've chosen the title for our correspondence section (Vital Signs) to reflect that letters from the readers are proof positive that our 'patient' is still living.

With this issue we also initiate a number of exciting new series. Last year when I took over the position as editor and began thinking about topics, there were two which stood out in my mind as being particularly important for the journal: medical writing by non-native English speakers and freelance issues. It took a little cajoling but here we are with our first offerings in these series. Although many people consider medical writing to be an exclusive preserve of native English speakers, the reality in Europe is otherwise, as those of you who attend EMWA conferences will know. The non-native English speakers among us, however, tend to keep a fairly low profile (with the exception of Leen Vanherle) and so both to provide greater service to them and to inform those of us who are native speakers about their concerns, I am thrilled to present Hilde Joosen's piece. Freelance writers represent another important but somewhat neglected minority of the EMWA membership. In trying to make this journal of interest and relevance to all members, it's also very important to address their issues and thus we present an article from the AMWA Journal by Cathryn Evans which offers a sample freelance contract. This kind of really practical information is an important addition to the viewpoint and opinion pieces we usually run. And speaking of practical, we kick off our "Key Pharmaceutical Documents" series with a piece by Judi Proctor on the Patient Information Sheet featuring a checklist of information to be included which is used by an actual ethics committee.

Finally, this issue marks the long-awaited return of the notorious EMWA journal humour column. I won't presume that it will ever again reach the exalted heights (or was it depths) to which the legendary Keith Veitch, in the spirit of Monty Python and Benny Hill, brought this column in days of yore (who will ever forget the Medical Writer's exam or the half-baked advice column?), but I did feel that it was a tradition that just couldn't be denied. I hope you enjoy it and don't find it too offensive (that would be a break with tradition already), and submissions are, of course, more than welcome (and can be made anonymously).

Barry Drees

President's Annual Report: 1998-1999

By Gerold Wilson

The year and a few months since the excellent conference held in Madrid, ably organised by Ben Young, has been one of the most significant periods in the history of EMWA. The Association has grown both in the size and breadth of its membership and has developed an organisation and structure to ensure continuing success in serving medical writers throughout Europe in the future.

Structure: During the year, the structure of EMWA has been re-ordered. Formerly EMWA had no legal basis, only a constitution. This was unsatisfactory in that members had no legal standing and there were problems with opening a bank account in many European countries (though not in the UK). After negotiating something of a legal maze, EMWA became incorporated as a company limited by guarantee. There are no shareholders or stockholders, but every member of EMWA is now a member of the company. The company cannot pay dividends to members and no-one can profit from the company. The company can make money from bank investments for the general good without any individual such as the treasurer being liable for the tax.

By establishing EMWA as a legal entity in its own right we have helped to secure stability into the future. The main part of the constitution, incorporated in the memorandum and articles of association, is legally binding. We have to stick to rules. The annual business meeting at the conference becomes the annual general meeting of the company and is sovereign. The committee are "the board of directors" of the company and responsible to the AGM. Everyday issues can be dealt with informally.

Administration: An important step in the more professional management of EMWA which occurred in Barry Drees' year as President was the appointment in October 1997 of an administrator/secretariat in the person of Phillipa Clow. With the location of the secretariat in the UK it made sense for the bank account to be located in the UK also. The EMWA bank account for several years was a personal account of the treasurer held in Switzerland. A new bank account was opened on 20 March 1998, all funds transferred from Switzerland and the previous account was closed on 6 August 1998. We should record thanks to Phillipa and to treasurer Barbara Grossman for their efforts in this area.

Education: The conference is the main educational event of the year and we are indebted to Julia Cooper for her hard work in organising a broader and more extensive programme for Copenhagen than we have ever attempted before. Julia has also played a part in our continuing contacts with the American Medical Writers Association and dealt with many of the difficulties which appear inherent in this relationship. Although there has been no progress in establishing academic links with a university or other institution for a masters programme, we have moved towards establishing EMWA accreditation of its own programmes.

Executive Committee proposed establishing an EMWA continuing education scheme along similar lines to the AMWA Core Curriculum. The details of the scheme will be as follows:

President's Annual Report

- The EMWA continuing education scheme will require completion of workshops (with homework) on a range of subjects. This will include workshops on topics relevant to medical writing in Europe as well as topics similar to the AMWA core curriculum.
- Any workshop credits obtained as part of the AMWA core curriculum will be recognised under the EMWA scheme.
- Workshop leaders will be appointed by an EMWA education committee. The composition of this committee was discussed at the AGM. This committee will also have the power to give the EMWA stamp of approval to trainee writer schemes run by other organisations.

The Executive Committee feel that it is time to set up a medical writing education scheme within Europe, to meet the needs of European writers and enable members to obtain accreditation by attending workshops in Europe. We now have sufficient workshop leaders within EMWA to get such a course off the ground. If we obtain a mandate from the membership, we could get things moving in time for a one-day meeting planned for later this year. Neither the annual conference nor smaller meetings would be possible without the contributions of speakers and workshop leaders who give freely of their time and great expertise. EMWA and its members are in their debt.

Links with other organisations: Keynote speaker in Madrid was the deputy editor of the Lancet, Dr David Sharp. This was a useful meeting because of David's role in EASE (European Association of Science Editors). We have subsequently discussed a reciprocal arrangement whereby EMWA and EASE members can attend each other's meetings at member rates. The next major EASE meeting is in Tours in May next year. We have also initiated discussions with AMWA (Australia) and DIA along similar lines.

Press and public relations: David Sharp also helped raise awareness of EMWA by commenting on the Association in a Lancet leading article. Not all EMWA members would have been in agreement with every thought expressed and several of David's points were answered in correspondence. Our PR officer, Jane Stock, reports that EMWA has, in addition to the Lancet reference, been mentioned in BrAPP newsletters and ACRPI newsletters. It has not been feasible to extend PR activity into other areas of medical writing such as communications agencies until our conference supported these types of writing more. Agencies appear interested, and many use our website, and so following the Copenhagen conference it may be possible to spread the PR net wider.

Membership communication: It has been the overriding concern of the Executive Committee throughout the year to provide our members with value for money. Two significant ways in which this has been done have been the launch of EMWA's magazine as *The Write Stuff* and the continuing excellence of the EMWA website. Our thanks go to Barry Drees and Marian Hodges for the really great effort and work that they have put into these important parts of the Association's activity.

Membership: In August 1998 paid-up membership was 161 members, 141 of whom were also AMWA members. There may also have been a number of people who had not paid membership at that time and we estimate that these people would have taken our operational membership at that time to about 190.

President's Annual Report

Less than one year later, Phillipa Clow and our former membership officer Debbie Jordan reported that we currently have 261 members of whom 141 are AMWA members. EMWA members reside in 19 countries, Austria, Belgium, Denmark, England, France, Germany, Iceland, India, Ireland, Italy, Netherlands, Norway, Singapore, South Africa, Spain, Sweden, Switzerland, Scotland and USA. The harmonisation of membership invoicing to 30 June 1999 was very successful and there are now only a handful of members to remind. Membership has grown mostly through personal contacts and will continue to grow if members resolve not to keep EMWA a secret. It is very important to spread awareness of EMWA, if only by pointing colleagues and acquaintances to the website. There will be plenty of spare copies of the programme for next year's conference, which can be sent to anyone that any member suggests.

Sponsorship: Finally, to sponsorship. We must record our gratitude to those commercial organisations which support EMWA and in particular to those involved in the conference. Novo Nordisk's sponsorship of the Copenhagen conference has extended beyond finance in the persons of Mary Ryan and Susanne Wedderkopp who have contributed so much to the organisation of the conference on the ground and in sorting out everything from the hotels to meeting rooms. Our special thanks goes to them.

Sponsorship is very important for EMWA and is rather static at the moment. For the pharmaceutical industry, in particular, sponsorship and support of EMWA represents excellent value for money. Any comparison between the costs and content of an EMWA meeting and similar commercial conferences bears this out. In terms of education of medical writers, EMWA is really the only game in town. Our problem is that, while the industry as a whole may appreciate the value of the service which EMWA performs, individual companies may take some persuading that they should dip into their own corporate pockets. A major sponsor is still needed for next year's conference, and continuing patrons are being sought. Everyone can help by pinpointing the key individuals in companies who could consider sponsorship.

Department of Corrections - Winter 1998/99

The first paragraph on page 17 of the article "The Future of Medical and Technical Writing" by Stephen de Looze had two lines deleted prior to printing. The correct text should read,

"There is a well-known Chinese saying about the journey of a thousand miles beginning with a single step. What the saying does not describe is what happens if your single step is in the wrong direction. If you are five hundred miles down the wrong road before you notice it, you are in big trouble, at least as far as deadlines are concerned!"

The official name of the publication of the Australian Medical Writers Association is <u>AMWA News</u> and not the <u>AuMWA Journal</u> as stated in "The Editor's Red Pencil" on page 3.



You had to be there! The Eighth Annual Meeting in Copenhagen

by Fiona Swain

At the end of each annual meeting, the old-timers can be heard to declare "This year's conference was the best so far!" and they'd be right. As EMWA goes from strength to strength, so does our annual meeting. With its best attendance yet (120 delegates) and a more varied programme than ever before, we were in for a real treat as the conference lived up to the motto of the city of Copenhagen, "Wonderful, wonderful".

For newcomers there were opportunities to make new contacts and discover the fellowship that exists in EMWA, the camaraderie that comes from meeting other writers with the same aims and ambitions, problems and challenges. For old-timers there were opportunities to renew friendships and discover how many of us have changed companies or gone freelance over the last year. For all, there was the tremendous opportunity to learn the latest techniques of our art, to brush up on skills

learnt some time ago and to discover more about other areas of medical writing.

The first two days of the meeting were packed with an array of workshops — at least three to choose from at each session. Whether it was to learn about project management, brush up on sentence structure, delve into the complicated

Discover the camaraderie that comes from meeting other writers with the same aims and ambitions, problems and challenges

world of pharmacoeconomics or find out how to write better pharmaceutical copy, there was something for everyone. The workshop leaders were, as always, of the very highest calibre and among the most experienced in our profession. As those who have been to the annual meeting know, these dedicated people speak with an enthusiasm that is hard to resist. This is not a conference where the delegates fall asleep!

Our keynote speaker on the last day was Peter Bonne Eriksen, Vice-President of Development at Novo Nordisk. He spoke about the future of the pharmaceutical industry past the year 2000, giving us some of his own predictions of how the industry might change. He suggested that the giant pharmaceutical companies may split into smaller, specialist companies and that we may see more direct advertising/selling to the patient in Europe. He did, however, point out that predictions can be unreliable and that the totally unpredictable can happen, for example, who predicted that the Berlin wall would come down? One thing is sure: there will be exciting changes ahead.

After the keynote speech, Alistair Reeves from Hoechst Marion Roussel gave a presentation on the use of Documentum as a document management tool and gave us some sound advice on the Dos and Don'ts of using such a system. It seems such tools can be of benefit when used properly but that there is still room for improvement on the software front.

One of the benefits of the annual meeting is the opportunity for networking and, to this end, the social programme also plays an important part. This year we were sponsored by Novo Nordisk, who not only provided financial support but gave of their time to ensure we enjoyed ourselves. The conference dinner, in the beautiful Tivoli gardens, was a success. Those who lasted the duration will testify that the most memorable thing about the evening was the firework display... and the close proximity of the spectators to the action (some of the more cowardly among us were seen cowering behind the nearest large tree). On another evening, we had a choice of guided tours: the zoo, Christiania (an alternative hippy commune in an abandoned military barracks) or the city by bike. The sun shone all week and Danish pastries, lager (probably the best in the world) and marinated herrings were all in abundance (the herrings being slightly less popular than the beer and pastries but all part of the experience).

As always, a host of volunteers put in a lot of hard work, for which we were all grateful. The business meeting ran smoothly under the capable hands of Geoff Hall, our new president. EMWA took an important step in officially becoming a company limited by guarantee and held its first annual general meeting as such. Keith Veitch was elected as Vice-President and Julia Forjanic Klapproth as Membership Officer. No doubt we will be hearing more from both of them. All that remains to say is that if you were there in Copenhagen, you have your smelly bag to remind you of a great conference. If you weren't there, too bad you missed it, but next year in Dublin promises to be even better. . . See you there!

Fiona Swain 42 Walter Road, Wokingham Berkshire, RG41 3JA, UK fiona@swain.u-net.com

More articles about the conference including transcripts of the plenary sessions will be appearing in *TWS* throughout the coming year.





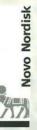
Susanne Wedderkopp, Novo Nordisk Conference Manager



Out front of the restaurant

We at Novo Nordisk send our warmest regards to all the delegates at the EMWA meeting in Copenhagen.

It was a pleasure sponsoring the meeting and seeing you all here in Copenhagen.



Novo Nordisk A/S is the world leader in insulin and diabetes care and also manufactures and markets a variety of other pharmaceutical products. Furthermore, the company is the world's largest producer of industrial enzymes. Headquartered in Denmark, Novo Nordisk employs approximately 15,000 people in 61 countries and markets its products in 179 countries. Its B shares are listed on the stock exchanges in Copenhagen, London and Zurich. Its ADSs are listed on the New York Stock Exchange under the symbol "NVO". For further company information, visit Novo Nordisk on the World Wide Web at http://www.novo.dk

A panel discussion



Serious business...





The Lighter Side: The Strange World of Adverse Events

Collected from various sources by numerous people and sent to The Write Stuff by Julia Cooper

Here is a small sample of some of the more outrageous, interesting, bizarre, and/or humorous adverse events that people have seen reported in the pharmaceutical industry. These were on a list that was being e-mailed around and so we can't vouch for authenticity, but some are so outrageous that they have to be true. The actual text supposedly appearing on the Case Record Form is given in bold and the TWS editorial comments are italicised. If any of you have your own favourite events, please send them in and we can see what else is waiting for us out there (to be continued).

This is my all-time favorite:

"Patient feels like dressing up as a clown and throwing himself off a bridge." A depressed patient dressing up like a clown sounds like a cure! (From an antidepressant study conducted in France)

"Restless legs, stubbed toe; slammed finger in car door; feels woozy; dreams of worms; pimples; drunk feeling."
Restless legs, Dreams of worms? (Source unknown)

"An elevated creatinine kinase due to a 'hickey' that covered the male's chest." Covered the male's chest, what was his lover, a giant squid? (Source unknown)

"Bite on breast by co-worker."

The patient was a woman, I don't even want to know what she did for a living. (Source unknown)

"Irresistible urge to go out and purchase a baby grand piano."
(From an antidepressant study)

"Woke up in night, grabbed wife's hand and hit her." (Source unknown)

"Alteration of taste of semen."
(Source unknown, thank goodness)

"Alcohol binge"; "Dopey feeling (slower thinking)"; "Hair loss, hands and wrists"; "Buffalo hump"; "Felt like a zombie."

Hair loss from the wrist? Sounds like a scene in a monster movie (Reported separately, from an AIDS study)

"Dislike of salads!", "Abdominal pain in left arm!", "Died in argument about sheep!"

(Reported separately, source unknown)

by Cathryn D. Evans
Reprinted from the AMWA Journal, Vol 13, Nos. 2 and 3, 1998.

I have received numerous requests to publish sample contracts for freelance writers. The following is just one example of a contract specific to projects negotiated on an hourly consultation basis for pharmaceutical, biotechnology, or other companies. The language is typical of many companies' legal departments because this is the source of most contracts of this type. Obviously, many variations of such contracts are possible. Sample contracts between a writer and publisher - as well as for fixed-fee projects - will be presented in future columns. To this end, contributions are encouraged from readers, along with any comments on the sample printed here.

COMPANY desires to retain Writer as a consultant to assist in the development of XYZ Product on the following terms and conditions:

- 1. Writer agrees to consult with [Name of client contact], or whomever COMPANY may designate by telephone or in writing, in relation to XYZ Product. Writer's responsibilities as a consultant include:
 - to provide communications services, including planning, organizing, writing and editing for clinical study reports, scientific publications, product monographs, and/or scientific presentations related to XYZ Product as mutually agreed upon with COMPANY.
 - to provide other consulting services in relation to the XYZ Product as COMPANY may request from time to time during the duration of this Agreement.
- 2. It is understood and agreed that COMPANY is contracting for Writer's services hereunder; if such personal services are not available for any reason, COMPANY may terminate this Agreement immediately. In such event, COMPANY agrees to pay all outstanding invoices within 30 days of receipt of such invoices.
- 3. It is understood and agreed that COMPANY will provide all relevant background material (or approve expenses for Writer to obtain such material from subcontractors) involved in a specific project and that, prior to any publication, distribution or submission of the material for review and/or publication, COMPANY is solely responsible for the approval of statistical and scientific accuracy and completeness of written material provided by Writer.
- 4. Writer will act as consultant and writer/editor and agrees that the name(s) of Writer or any of its principals, employees or affiliates will not be listed as author(s) on any publications that result from such consultations, unless agreed upon mutually by COMPANY and Writer.
- 5. COMPANY agrees to indemnify, defend and hold Writer free and harmless from and against any and all liability, including but not limited to loss, costs, damages, attorney's fees and expenses of whatever kind or nature resulting from written or published material on the XYZ Product. Should writer be asked to participate as a

witness in a deposition or trial connected with the XYZ Product, COMPANY agrees to reimburse Writer for any and all costs, liability, damages, attorney's fees and expenses associated with such procedures, including but not limited to the cost of materials/services requested and for Writer's time involved in such activities at the rate of X/hr or Writer's hourly rate at the time of the request, whichever is higher.

- 6. As full consideration for Writer's services hereunder and for Writer's agreement to the terms and conditions hereof, COMPANY agrees to pay Writer X for each hour of consultation, as mutually agreed upon by telephone, FAX or letter, between Writer and COMPANY prior to initiation of work. COMPANY will also reimburse Writer for reasonable out-of-pocket expenses associated with each project (including, but not limited to, literature searches, copying services, word processing services, graphic illustration, FAX and electronic-mail transmissions, long distance, and approved travel expenses incurred while executing a specific project). Fees are payable within 30 days of COMPANY's receipt of an invoice of itemized services. COMPANY further agrees to pay a 10% late fee for invoices that are not paid within the 30-day period. [see below for an alternative wording for fixed-fee projects]
- 7. Writer agrees that unrestricted copyright will be transferred from Writer to COMPANY for all projects executed on XYZ Product after Writer has received payment for all invoices associated with a specific project, unless other agreements are mutually agreed upon in writing between COMPANY and Writer.
- 8. Any information, inventions or discoveries (whether patentable or not), product innovations, suggestions, ideas, communications and reports conceived, reduced to practice, made or developed by Writer relating to the XYZ Product as a result of Writer's services under this Agreement shall be promptly disclosed to COMPANY and shall be the sole property of COMPANY. Writer agrees to execute, upon COMPANY's request and at COMPANY's expense, such documents and to take such other actions as COMPANY deems necessary or appropriate to obtain patents in COMPANY's name covering any of the foregoing.
- 9. During the term of this Agreement, including any extension thereof and 5 years thereafter, Writer shall exercise due care to prevent the unauthorized disclosure of Confidential Information. Confidential Information shall include all Information concerning COMPANY and XYZ Product disclosed to Writer by COMPANY, or developed as a result of Writer's services under this Agreement, except any portion thereof which:
 - is known to Writer before receipt thereof under this Agreement, as evidenced by written records;
 - is disclosed to Writer after acceptance of this Agreement by a third party who has a right to make such disclosure; or
 - is or becomes part of the public domain through no fault of Writer.

Further, during the term of this agreement, including any extension thereof and 5 years thereafter, Writer shall not use Confidential Information for any purpose other than that indicated in this Agreement without COMPANY's prior written approval.

- Writer agrees not to disclose the existence of this agreement or use the name of COMPANY in any advertising or promotional material without COMPANY's prior written approval.
- 11. Writer agrees not do disclose to COMPANY any information which is confidential and/or proprietary to a third party.
- 12. Writer warrants and represents that the terms of this Agreement are not inconsistent with other contractual and/or legal obligations Writer may have, or with the policies of any institution with which Writer is associated including, but not limited to, policies regarding the administration of grants and funded research.
- 13. This agreement shall be effective through [Date] and may be extended by written agreement signed by the parties. Either party may terminate this Agreement without cause upon written notice to the other party 30 days prior to termination. Termination or expiration of this agreement shall not effect any rights or obligations which have accrued prior to termination. Upon completion of Writer's consultation, termination or expiration of this Agreement with COMPANY, Writer shall return to COMPANY all Confidential Information, data and materials provided to Writer by COMPANY, or developed by Writer as a result of consultation services, as requested by COMPANY. COMPANY will reimburse Writer for any expenses associated with returning or destroying confidential material.
- 14. Writer's status under this Agreement is that of an independent contractor, and Writer has no authority to bind or act on behalf of COMPANY except as otherwise expressly stated herein. Writer may not assign this Agreement to a third party without COMPANY's prior written consent, and any attempted assignment shall be null and void. COMPANY may not assign this Agreement to a third party without Writer's prior written consent, and any attempted assignment shall be null and void.
- 15. As an independent contractor under this Agreement, Writer shall not be entitled to participate in any benefit plan or program for employees of COMPANY. However, nothing contained in this agreement shall prevent or preclude Writer from other benefits to which Writer may be entitled under various COMPANY retirement and benefit plans by virtue of any employment with COMPANY prior to the effective date of this Agreement. Writer shall be responsible for and agree to comply with obligations under national tax laws for payment of income and self-employment taxes. Writer shall have no authority to bind or act on behalf of COMPANY except as otherwise expressly stated herein.
- 16. This Agreement contains the entire understanding of the parties with respect to the matters herein contained and supersedes all previous agreements with and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.
- 17. This Agreement shall be governed by and construed in accordance with the laws of [use whatever is appropriate].

An alternative wording for fixed-fee projects replaces item 6 above:

6. Writer will produce an educational monograph for a single audience on "Topic" according to a complete and annotated outline supplied by COMPANY, with background material also supplied by COMPANY and specifically keyed to the outline. The monograph will be addressed to a single audience (i.e., patients with X disease). The final length will be approximately 80-100 double-spaced manuscript pages, or 32-40 typeset pages.

COMPANY's annotated outline will include (1) a working title of the monograph; (2) titles for each section, presented in the order of their required appearance; (3) sub-titles under each section, if relevant; (4) under each section, a brief overview of what the section and its sub-sections should contain; and (5) identification of the reference sources for each section.

Writer will supply text only, with suggestions for charts, graphs, and/or illustrations. The fixed fee for writing will be X,000-X,000, depending on the scope and complexity of the outline and background material, as well as the final length of the monograph. Direct out-of-pocket expenses (including but not limited to telephone, copies, FAX, postage, shipping and/or couriers, word processing fees, disk conversion and downloading, literature searches as required, draft charts and tables, etc.) will be reimbursed by COMPANY upon invoice submitted by Writer.

Contingencies for the fixed fee include the following: work will commence only after *all* material has been given to Writer; the fee will include a first draft plus one reasonable revision; the one revision will be made from a single review copy (i.e., multiple reviewers' comments have been reconciled by COMPANY before sending the revised markup to Writer); and the requested revisions must be returned to Writer within four weeks of submission of the first draft. A "reasonable revision" means minor editorial changes only; structural changes or new material not included in the original outline will be charged hourly at X/hr. Similarly, changes submitted on more than one copy of the manuscript, or later than four weeks after initial submission, will be charged hourly.

The fixed fee does not include instructional design, examinations, or final page layout and art; formatting of the manuscript will follow your outline. The payment schedule will be as follows: one-third in advance (prior to commencing work), one-third upon submission of the first draft, and one-third upon submission of the first revision; expenses for each part of the cycle will be included in the relevant invoice. Invoices for hourly charges will be submitted once a month, or upon completion of a revision cycle. After payment of the advance, all invoices must be paid within 30 days of the date of the invoice, with a 10% late fee for amounts not paid within that time.

Cathryn D. Evans Chandos Communications 945 Alice Lane Menlo Park, CA 94025, USA savonna@aol.com Fax: (+1) 650 326 0327 Cathryn D. Evans has been a freelance writer and communications consultant in California since 1980. She is a past president of AMWA and a recipient of the Golden Apple Award. She has given 17 workshops on freelancing and many others on various aspects of medical communications.



The Non-natives are Restless:

A Call for Dialogue Between Native English-speaking and Non-native English-speaking Medical Writers

by Hilde Joosen

When I was asked to write an article about my experiences as a non-native English-speaker doing medical writing in English, my first reaction was one of reservedness and doubt. Why would I, as a native Flemish-speaking Belgian, spend my scarce spare time writing an article — in English — for a highly critical target group, i.e. medical writers, of whom the majority are native English-speakers.

However, almost immediately, I recalled the relief and hope that I had felt when I first heard about the possibility that a new EMWA workshop was going to be organized: Writing/editing for non-native speakers. From several conversations at previous EMWA meetings, I also knew that I would certainly not be the only one interested in this somewhat delicate topic. So, here is my story about how I got started in medical writing and more importantly, how I have survived.

In January 1991, I started to work at Janssen as a data reviewer. Since my contract was only a temporary one, I kept looking for a permanent position. Due to reorganizations within our department, I began to write my first report a few months later; officially, I was still a data reviewer in the Clinical Biostatistics group. I started from the few relevant examples that were available in those days, and worked more or less on my own. At that time, most of the medical writing at Janssen had been done by

my current boss. So, soon, I went to him and got my first on-the-job training. One could say that we were both in a unique position: while I was still part of another department, he could evaluate my skills as a potential medical writer and I could become familiar with the job and, perhaps, end up with a permanent position.

Being a native English-speaker in itself is no guarantee for being an excellent medical writer, and being a non-native English-speaker does not imply that one is doomed to be a poor medical writer

My scientific background and experience as a data reviewer, especially my well-developed

sense of both accuracy and quality and a quick understanding of the writing process amply outweighed the — minor and infrequent — comments that I received on language as a junior writer. One has to keep in mind though, that I started as a medical writer almost eight years ago in a Belgian pharmaceutical company with hardly any native English-speaking employees of any kind, let alone native English-speaking medical writers. Since the main part of my job was to write clinical research reports, I quickly got used to the technical and rather standardised language that is inherent in report writing.

The Write Stuff

The Non-natives are Restless

Fortunately, I had a 'living dictionary' at hand as I shared an office with Leen Vanherle, former president of EMWA, who had studied at the University of London. Obviously, there was also a set of standard dictionaries at my disposal, such as The Collins English Dictionary, The Webster's New International Dictionary and Roget's Thesaurus, among others. What was very useful were the private lessons that I took from a Canadian editor-colleague. He edited texts that I had written and gave me advice on how to improve them. Unfortunately, this training was brief because he left shortly thereafter for another department. In line with these lessons, 'Dear Edie' used to be one of my favourite topics in the AMWA Journal.

What I have personally experienced over the years as the main challenges are the editing of texts (e.g. protocols or specific sections of a report) written by other non-native English-speaking colleagues like statisticians or clinicians; discussions with native English-speaking colleagues (e.g. team members on the other side of the ocean or fellow EMWA members at meetings); the writing of good, less standardised and less technical prose (this text seems like a good example to me); grasping the finer points of the English language; and, finally, convincing native English-speakers that as a non-native you're often more critical of what you write (you're inclined to weigh your words more carefully) and that the quality of your work is as good as (or sometimes even better than) that of some native English-speakers.

We medical writers are all expected to produce high-quality written scientific documents, usually in English. The diverse skills that are needed to achieve this include scientific knowledge, writing ability, meticulousness, flexibility, team spirit, time and project-management skills, word-processing competence, diplomacy, and, of course, linguistic skills. We all have a combination of these in different proportions, with our own strengths and weaknesses. What I am trying to say is that being a native English-speaker in itself is no guarantee for being an excellent medical writer, and being a non-native English-speaker does not imply that one is doomed to be a poor medical writer.

We all want to optimize our professional skills. Fortunately for us, the ever-increasing group of non-native English speaking medical writers in EMWA, the first steps have already been taken. Thanks to the Conference Organising Committee, the workshop Writing/editing for non-native speakers was offered for the first time in Copenhagen. And now thanks to the Editor of The Write Stuff, our enthusiastic ally in this dialogue, we now have our own series. As a next step, I would like to ask all of you — native as well as non-native speakers — to provide me with any constructive ideas, comments, suggestions or reactions regarding this topic. With our combined efforts, we can strive for one of the main aims of EMWA, i.e. to provide education by and for its members. Your contribution, no matter how small, could mean an important step forward. This concerns the profession of each one of us, so don't wait until tomorrow: write to me today!

Hilde Joosen Janssen Research Foundation Turnhoutseweg 30 B-2340 Beerse, Belgium hjoosen@janbe.jnj.com Tel: (+32) 1460 5106



Key Pharmaceutical Documents I: The Patient Information Sheet

by Judi Proctor

One of the most common reasons for a Research Ethics Committee to return a study protocol to the researcher for amendment is because the patient information sheet (IS) and consent forms are inadequate or incomplete¹. As anyone who has ever been involved with submitting protocols to ethics committees will know, there is an ever-increasing demand for uniformity of paperwork. Although there are ICH guidelines for the content of an IS (ICH-GCP Guidelines E6, Section 4.8), they are vague and open to interpretation.

There is a small working group currently formulating advice for the UK on good practice for applicants in preparing ISs and consent forms. They are working towards establishing guidelines and a standard format for patient information sheets and consent forms that will comply with ICH-GCP requirements.

An IS is written to inform a potential study patient about the study in language that they can understand, and that means simple. When writing an IS, you should assume that the average reading age is between eight and ten years of age. Readability (The Flesch-Kincaid grade level on Microsoft Word 7.0) should be between 60 and 70% and the Flesch Reading Ease score should be between 7.0 and 8.0. Although the language must be kept simple, the temptation to leave out complex information should be

resisted. You must also make sure that all the information provided is correct and not misleading. Jargon is best avoided at all times, particularly if a study is multinational as the IS will need to be translated and jargon does not translate well.

Ethics committees tend to prefer short ISs to longer ones that they have to wade through to determine whether all aspects of the ICH-GCP guidelines have been followed. You should aim

One of the most common reasons for a Research Ethics Committee to return a study protocol to the researcher for amendment is because the patient information sheet and consent forms are inadequate or incomplete

to make an IS no longer than two pages. If it is much longer, patients might only get halfway through and stop reading. If however the nature of the study demands that the IS be very long, then a letter of invitation to the patient should also be provided.

It is best to use a font size of at least 11 pt. Smaller font sizes will reduce readability, which is especially important for patient populations with elderly or other patients with poor eyesight. A highly compressed text using a small font would be especially difficult to read in view of the claim that when you read text, you don't actually read the words, you actually read the "white" space around the letters.

The Write Stuff

The Patient Information Sheet

One approach is to write the IS as a series of questions that you might expect a patient to ask together with the most informative responses that they could receive. The questions should be written in bold type to distinguish them clearly.

As consent is a voluntary agreement based on adequate information, research ethics committees must do their best to ensure that a researcher provides this². The South West Multicentre Research Ethics Committee (MREC) in the UK has produced an IS checklist to assist the chairperson of the ethics committee in checking that requirements contained in the "MREC Information for Researchers Pack" and the ICH-GCP Guidelines have been addressed in the application under consideration. Although many research ethics committees currently issue their own guidance for researchers on writing ISs, using this checklist when writing an IS can greatly help in making sure that all the information is included.

South West Multicentre Research Ethics Committee

Patient Information Sheet Checklist

This list is intended to help the committee chair check that requirements contained in the MREC Information for Researchers Pack and the ICH-GCP E6 Guidelines have been addressed in the application under consideration (* indicates the item is an ICH-GCP requirement).

Section1: General

- 1. Is it printed on headed paper and given a simple title?
- 2. Is it a sensible length?
- 3. Is the language suitable?
- 4. Is the information offered comprehensive and accurate?
 - *Is the purpose of the study explained in a way that the research subject can understand?
 - *Are technical terms given and explained?
 - *Are alternative forms of treatment (including withdrawal of treatment when appropriate) clearly explained?
 - *Are the risks, side effects and benefits fairly weighted?
 - *Are all the implications of being in the trial, such as hospital attendances, procedures etc. made clear to the research subject?
- 5. Does the researcher advise the subject when direct payment is received by them for running the trial?
- 6. *Is there a statement about confidentiality?
- 7. Is a statement included about the availability of medication at the end of the trial?

The Patient Information Sheet

Section 2: The Welfare of the Research Subject

- 1. *Is it explained that involvement in the trial is voluntary and that the right to withdraw at any time is without prejudice to future treatment?
- 2. *Are the indemnity arrangements explained?
- 3. *Are expenses offered?
- 4. *Is there information about payment to research subjects where appropriate and the fact that payment is subject to tax?
- 5. Where involvement in the research is harmful to anyone pregnant, or likely to become pregnant, is this explained clearly?
- 6. Is the research subject's permission sought to contact their GP?
- 7. *Is a name, address and telephone number given in case of adverse side effects?

Additional ICH requirements

In addition to the above checklist, the following points should be made clear to the patient:-

- 1. That the trial involves research.
- 2. What the experimental aspects of the trial are.
- 3. What can reasonably be expected from participation in the trial. If there is no intended therapeutic benefit, this should be stated.
- 4. That monitors, auditors, ethics committees and regulatory authorities will have direct access to medical records for verification purposes, and that by signing the consent form they give permission this access.
- The duration of the trial and the likely length of time the subject will be asked to participate.
- 6. The approximate number of patients in the trial.
- 7. The foreseeable circumstances that would lead to a patient's involvement in the trial being terminated.
- 8. A statement promising to advise the subject if information becomes available during the trial that may affect the patient's willingness to participate.

Some trials involve healthy volunteers, for example phase I trials or contraceptive medication trials. In these cases, the volunteers are subjects, not patients. Therefore, the IS is a "subject information sheet" and the reference to "patients" must be "subjects" throughout.

The IS has two goals: to fully inform the potential patient about the study and to help them decide to take part in the study. If you can achieve both of these then you have satisfied your responsibilities to both the patient and the study sponsor.

References

- R&D Directorate , NHSE South Thames, September 1998
- 2. Hughes T, Foster Claire. Communication with the potential research subject, August 1997

Judi Proctor IBAH UK Wessex Business Centre, Bumpers Farm Chippenham, Wiltshire, UK ProctorJ@ibah.com Tel: (+44) 1249 440563 Fax: (+44) 1249 445614



From the Literature ... Information days (or daze)?

by Liz Wager

Information overload (for which, I guess, writers must take some blame) has spawned the discipline of information management. As I still rely on bulging box-files, the 'must be here somewhere' method of filing, and an ever worsening memory, I decided to read about this new topic.

I discovered a whole journal called 'Managing Information' which is aimed mainly at British librarians but had an interesting article on health information in the January/ February issue (Jan/Feb 1999, p29-32). This lists resources like electronic database publishers, evidence-based practice internet sites and medical news groups.

Even *The Lancet* had an editorial entitled 'The information wars' (16 Jan 1999, Vol 353, p. 164-166) which considered the merits of systematic versus narrative reviews and concluded that judgement counts even though we might wish it didn't. This is good news for medical writers, since it pushes further away the day when we shall be replaced by intelligent computers searching the web and automatically writing reports. Incidentally, the future for translators is also secure if my husband's success at automatic website translations is anything to go by. One site, detailing the merits of a German face cream, proclaimed (in translation) that it 'activated the journalist under the skin' — maybe I should try some.

On more serious matters, the first *BMJ* of 1999 (2 Jan 1999, vol 318, p. 46-47) carries a thought-provoking article about transparency, or rather the lack of it, in British medicine's regulations. The authors are concerned that plans outlined in a government White Paper put pharmaceutical companies' commercial interests before those of public health. I can't help thinking that the internet and the Europeanisation of drug registration will have more effect on freedom of information than national legislation, but these are interesting times. For another thoughtful analysis of the UK situation try the article by Roberts *et al* in *The Lancet* of 29 Aug 1998 (vol 352, p. 726-729 plus the editorial on p. 665).

Meanwhile, I'm sure I was going to include another fascinating paper in this column, but I just can't lay my hands on it ... maybe this information management isn't such a bad idea...

Elizabeth Wager Janssen-Cilag Ltd. PO Box 79 Saunderton, High Wycombe HP14 4HJ, UK lwager@jacgb.jnj.com

Tel: (+44) 149 456 7574 Fax: (+44) 149 456 7404



Vital Signs: Correspondence from our Readers

Dear TWS,

As someone who has been practising homoeopathy for a number of years now – both in the retail pharmacy environment when one is using the treatment primarily on a symptomatic basis and also as a practitioner when patients are treated constitutionally – I would like to make one comment on the statement that homoeopathic remedies do not cause side effects. This is not strictly true. Although in the conventional use of the term homoeopathic remedies are not considered to cause side effects, during treatment patients can experience side effects due to:

- aggravation which can lead to a temporary worsening of symptoms
- manifestations of previous medical conditions (Hering's Laws of Cure) e.g. a
 patient being treated for asthma may often experience a flare up of eczema as
 the disease works its way out of the body.

Likewise there are occasional instances when one would be advised not to use a particular remedy in certain conditions (contra-indications), e.g. Apis mel in pregnancy or Silica if the patient is fitted with a pacemaker.

Virginia Watson email:watsonv@ibah.com phone:+44 1249 440573

Dear TWS.

On behalf of the Children's Overseas Relief Fund (CORF), I wish to appeal to *The Write Stuff* readers who work for Pharmaceutical and Healthcare companies. CORF was founded by Mrs Jenny Skinner and became a registered charity (No. 1070467) in 1998. It provides aid to orphanages in Bulgaria and is also collaborating with the Bulgarian government to establish dance/colour/movement therapy programmes in the orphanages. Ultimately, CORF may instigate adoption or sponsorship schemes. CORF relies entirely on donations and money from fund raising events. All workers are voluntary and so all the money raised goes directly to the work with the orphans.

The plight of the orphans is truly desperate. The homes are usually very isolated. They are in a very poor state of repair and have only the bare necessities for furnishings. Dormitories are severely overcrowded and the children and staff have to suffer the indignity of sharing one toilet between approximately 30 people. Some of the children have physical and/or mental abnormalities. All have cropped hair to prevent lice and pale complexions resulting from poor diet and lack of fresh air. The orphanages are understaffed and when the budget runs out, the staff have to resort to begging in order to feed the children.

Vital Signs

CORF is aiming to send 1999 boxes of aid to six orphanages in Bulgaria on 23 July this year. Among other items requested for these aid boxes, the following medicines are desperately needed:

- 1) Oral antibiotics for respiratory tract infections i.e cephalosporins, macrolides and penicillins (paediatric and adult formulations the age range is 3 to 18).
- 2) Antitussive medicines (paediatric and adult).
- 3) Antiseptic creams.

I therefore urge all readers who work for companies which produce these medicines to encourage Medical, Marketing and Managing Directors to make donations. Companies can be assured of the following:

- 1) All exports of medicines are approved by the MCA.
- 2) All prescription only medicines will be given under the authority of visiting physicians.
- 3) All donated supplies will be stored securely under double lock in CORF's new warehouse in Bristol prior to dispatch to Bulgaria.
- 4) Prescribing information can be translated into Bulgarian if necessary.

Financial donations are always welcome. Thank you. If you can help, please contact Jenny or David Skinner at:

CORF

5 Bridges Court, Fishponds Bristol, BS16 5BY UK Tel/Fax (+44) 117 9652 143

Gerry Harnisch
Freelance Clinical Scientist
12 Willow Way, Motcombe
Shaftesbury, Dorset, SP7 9QH UK
Tel/Fax (+44) 1747 850331
gjharnisch@aol.com

FREELANCE MEDICAL COMMUNICATIONS

I have 14 years experience in the pharmaceutical industry of which 12 have been spent in clinical research in a diverse range of therapeutic areas. I have a fully equipped home office with PC (Windows 95 and MS Office 97 software), scanner, fax and photocopier. I am available for short and long term medical communications assignments in the following areas:

meeting reports, training material, monographs, news copy relating to the global healthcare industry, journal articles, reviews, patient information leaflets, health education leaflets, prescribing information, abstracts, book chapters, proofreading, editing, study reports, expert reports.

I provide a prompt, efficient, high quality service at competitive prices. CV and writing samples available on request. Please contact:

Gerry Harnisch

12 Willow Way, Motcombe, Shaftesbury, Dorset, SP7 9QH, UK

Telephone/Fax: +44 (0)1747 850331

E-mail: GJHarnisch@aol.com

Meetings of Interest

by Sarah Heritage

The following list is presented as a service to EMWA members and is not meant to be complete. EMWA does not endorse these meetings in any way. Those having the **[EMWA]** symbol include presentations from EMWA members. If you would like to have something listed here to share with other members, please contact Sarah Heritage, Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK. Tel: (+44) 1483 554 296; Fax: (+44) 1483 554 826

Data	Mosting/Spanor	Location
Date	Meeting/Sponsor	Location
Jun 1-2 and Nov 10-11	Understanding Pharmacokinetics: An Introduction Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Jun 8-9 and Nov 23-24	Medical Statistics for Non-statisticians Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Jun 23-24	Effective Medical Writing Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Jun 28 [EMWA]	Integrierte Studienberichte nach ICH Kendle Munich Stefan-Georg-Ring 6, D-81929 München, Germany Tel: (+49) 89 993913 0; Fax: (+49) 89 993913 160; info.muc@kendle	Munich, Germany
July 7-9	Pharmacokinetics in Drug Development TPI Ltd. 32 Station Approach, West Byfleet, Surrey, KT14 6NF, UK Tel: (+44) 1932 351 733	London, UK
Sep 8-10	Foundation Course in Medical Writing PPD-Pharmaco, Maxwell Courses Ambassador House, 8 Carlton Crescent, Southampton, SO15 2EY, UK Tel: (+44) 1703 724 800	London, UK
Sep 30	How to Write an Expert Report Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Oct 7-8 [EMWA]	Medical/Technical Writing and Ass. Technologies Drug Information Association Postfach 4012 Basel, Switzerland Tel: (+41) 61 386 9393; Fax: (+41) 61 386 9390; diaeurope@stepnet	Dublin, Ireland .de

Coming next issue . . . (Summer)

Simultaneous International Issue

(Together with AMWA Journal and AMWA News)

Scribbling in the Antipodes, by Peter Hobbins The State of Biomedical Communications in the US, by Robert Jacoby Medical Writing in the Old World, by Barry Drees

We all know that there are medical writing associations in North America, Europe and Australia, but what are the memberships of these organisations like in terms of member backgrounds, careers, and goals. Find out about our sister organisations from around the world in a first-ever simultaneous publishing event.

☞ NEW FEATURE!

In the Bookstores

Karen Shashok

How many of you have been struck by the lack of communication between scientific-technical-medical translators and editors, professionals in applied linguistics, and other technical writers? An EMWA member reviews Nancy L. Hoft's *International technical communication*. How to export information about high technology, which shows how all these groups can contribute to effective translation and localization.

Why Write Now?

Jane Mitchell

Thinking of going freelance? Need a way of communicating your brilliance to potential customers? How about producing a regular newsletter? Sound too daunting? Read about the trials and tribulations of EMWA's very own Jane Mitchell and the newsletter of her freelance medical writing business, *Write Now*.

What's it All About?

Adam Jacobs

As you slog through endless case narratives for a Clinical Study Report or hack your way through the jungle of mouse and rat data for an Investigator's Brochure, it's easy to forget the point of what we do and to see our work as like that of any other technical writer. Here we present a personal reflection on the medical part of medical writing.

We will also have our regular features (The Editor's Red Pencil, From the President's Desk, Meetings of Interest, From the Literature, etc.). Until then.

EMWA Executive Committee

President:

Geoff Hall

58 Church Road, Worcester Park, Surrey, KT4 7RW, UK Tel: (+44) 181 715 1368 Fax: (+44) 181 715 1369 medwritehall@worldscope.co.uk

Vice-President & Programme Manager:

Keith Veitch
R&D Management (B.60/H315)
SmithKline Beecham Biologicals
Rue de L'Institut 89
B-1330 Rixensart, Belgium
Tel: (+32) 2 656 9632
Fax: (+32) 2 656 8113

veitch@sbbio.be or keithveitch@compuserve.com

Education Officer:

Julia Cooper Parexel International Ltd River Court, 50 Oxford Road Uxbridge Middlesex, UB9 4DL, UK

Tel: (+44) 1895 864 403 Fax: (+44) 1895 864 323 julia.cooper@parexel.co.uk

Treasurer:

Barbara Grossman Covance 7 Roxborough Way Maidenhead Berks, SL6 3UD, UK Tel: (+44) 1628 548 182 Fax: (+44) 1628 547 333 barbara.grossman@covance.com

Website Manager:

Marian Hodges 6 Highfields Ashtead Surrey, KT21 2NL, UK Tel: (+44) 1372 275 053 marian@molesoft.demon.co.uk

Membership Officer:

Julia Forjanic Klapproth
Hoechst Marion Roussel
Clinical Development
Bldg. H840
D-65926 Frankfurt, Germany
Tel: (+49) 69 305 82982
Fax: (+49) 69 305 80070
julia.forjanic-klapproth.hmrag.com

Public Relations:

Jane Stock 97 Ashen Grove Wimbledon Park London SW19 8BJ, UK Tel: (+44) 181 241 1243 Fax: (+44) 181 241 0456 jane.stock@dial.pipex.com

EMWA Secretariat

Phillipa Clow, 10 Batchworth Lane, Northwood, Middlesex, HA6 3AT, UK
Tel: (+44) 1923 842 503 Fax: (+44) 1923 835 077
emwa@dial.pipex.com