NEWSLETTER

EMWA European Medical Writers Association

Chapter of the American Medical Writers Association

In this issue: **Summer/Autumn-1996**

The Editor's Red Pencil

Hello, hello, we're back again.....

After a long lay-off due to what has been an uncomfortably busy few months the EMWA Newsletter has finally hit the top of the to-do list. Having been volunteered to be the new Editor by Janice Beck I can finally put fingers (two actually) to the keyboard to get something produced. Sorry to all those folks out there who thought that EMWA had ceased to exist. I hope the contents of this issue prove otherwise, with details of the 1997 conference in Edinburgh, the sparkling new EMWA Web site and the opening address from our new President, Ben Young. Speaking if whom, if anyone knows where he has disappeared to (Spain was rumoured) let us know.

At this point I should emphasise that this Newsletter is for you, about you, and written by you. I do not intend writing for it and I am looking forward to receiving all of your contributions for future editions. After all, if you could not write you would not be a member of EMWA !! So lets make this a Newsletter to be proud of, to maintain the high standard which Janice has established. Take a break from that report and jot down your thoughts to share with us all. We are looking for articles on anything that will be of interest to the membership... so how about something on topics not necessarily related to the medical/pharmaceutical field, but which are common to all of us as a profession. As an example, I don't think I would lose any money betting that all of us regularly use word-processors. So what are your loves and hates about the latest computers and word-processing software? I can start the ball rolling with an "oldie"... I love Macintosh (even though this is being painfully typed out on a PC). Everyone has a right to their opinion, so share yours with us. Even send in those curious little suggestions that your spell-checker turns out every now and then...

Any submissions can be sent via ordinary mail or FAX, but ideally for those of you fully equipped for this electronic age, send it by e-mail to either of my addresses below. And while you have the modem connected, do a little Web-surfing and visit the great new EMWA Web site which has been lovingly crafted by Marion Hodges (see page 10 for details).

At the Berlin conference, once I realised that resistance was useless and I was going to have to edit the Newsletter, I said that this should be an easy job because all those professional writers out there will be able to provide tons of well-written, easily edited material for inclusion. Go ahead, prove me right!

Keith Veitch

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THE NEWSLETTER

First point of business is the title of this missive. We would like to have a descriptive title rather than just NEWSLETTER. After all, there cannot be many newspapers called NEWSPAPER. So how about something different. Suggestions are welcome from one and all, and if there is sufficient support I will arrange a prize for the winning suggestion. Some suggestions already received include the Red Pencil (which I have stolen for my column!!),

WordlyWise,
First Draft,
Dossier,
The Boiler Plate,
Deadlines,
Canary Dwarf,
Missing Link,
The Writer's Block,
Inkspot,
Doublespeak.

Job advertisements

In the current rapidly changing employment market we realised that using an infrequent (Sorry!-Ed.) platform such as the Newsletter is not an adequate service for our members. So all future submissions for job ads should be sent through the EMWA WWW page (see page 10), where the speed of turnaround could not be higher! However, we will continue to allow freelance members who wish to advertise their services in the Newsletter to do so when accompanied by a general article for inclusion as an example of their work. Of necessity, this will mean some editorial selection, but all will appear!

FIFTH INTERNATIONAL EMWA CONFERENCE

The 1996 International Conference held in Berlin on March 6-8 was the organisation's first 3-day event, and was attended by over 70 members from all across Europe as well as from North America and South Africa. A tremendous amount of work was involved to make the meeting a success. Special thanks go out to Schering AG for hosting the event, to EMWA Programme Manager Gerold Wilson and, of course, all the workshop leaders who travelled from far and wide to contribute. Furthermore, it cannot be emphasised enough that the guidance and support of AMWA Headquarters were essential to the success of the event.

The conference included the six workshops listed below, the first four of which were for AMWA Core Curriculum Credit.

1) Project Management - **Art Gertel**
2) The Author-Editor Relationhip - **Susan Eastwood** and **Valerie Moore, PhD**
3) Statistics for Medical Writers and Editors - **Thomas A. Lang**
4) Tables and Graphs - **Barry Drees, PhD**
5) The Process of Writing - **Tim Albert**
6) The Art of Freelancing - **Geoff Hall**

A number of innovations were tested at this conference. By popular demand, Art Gertel's project management workshop was extended to 6 hours, and was a smashing success. Barry Drees and Valerie Moore became the first EMWA members to provide workshops for AMWA Core Credit. Barry modified the existing programme of Tables and Graphs, and in doing so became the first to test the new AMWA guidelines for sanctioning both workshops and workshop leaders. To a large extent, the success of this experiment was due to the co-operative efforts of Lynn Alperin, AMWA Education Administrator.

We were pleased to welcome Dr David Jeffreys, Medicines Control Agency, UK, as our keynote speaker on March 7. He spoke on **The Enhanced Role of the Medical Writer in the New European Drug Registration Process**, and made it very clear what he intends medical writers, as documentation specialists, to be looking out for in dossiers. Dr Jeffreys is responsible for the assessment and licensing of all new active substance licence applications made in the UK, and has an instrumental role in the Committee on Proprietary Medicinal Products.

Kicking off the General Session on March 8 was a rousing panel discussion on the topics raised by Dr Jeffreys. Barry Drees led the international group consisting of experts from project management, regulatory affairs and, of course, medical writing. This was followed by a presentation from Susan Eastwood about Qualifications for Medical Writers and Editors. There was something for everybody, and the Session was well attended. In the afternoon, Joel Tau, AMWA President, was on site to give a special presentation of his vision for AMWA. As a professional organisation, AMWA should strive to double its membership by the year 2000; moreover, there is no reason why AMWA should not be THE leading organisation in its field in the foreseeable future. After the applause for Joel's presentation died down, a speech written by John Aitken, now Immediate Past President of EMWA, was delivered in absentia by yours truly, the author of this report.

After the talks, we got down to the business of business. Following my instatement as this year's EMWA President, we elected Barry Drees as President-Elect and Julia Spivack as Programme Manager. Barry and Julia will be organising next year's conference, details of which appear later in this issue. Two-year offices were not up for grabs this year, so Philip Cooper will stay on as Treasurer, and Leen Ashton-Vanherle will continue her good work as Education Officer. Keith Veitch was conscripted (kicking and screaming) to take over the Newsletter from Janice Beck, who did an outstanding job of redesigning and upgrading it last year. As an absolute bonus, Gerold Wilson has volunteered to take over the EMWA database, and will be in charge of Membership and PR for the coming year (or for as long as we can get him to do it!). The Newsletter and Annual International Conference are two of the mainstays of EMWA, but our new website promises to become one of the most exciting additions to the roster. On another front, productive discussions continue on the relationship between EMWA and AMWA, and the International Task Force hopes to present a working proposal in the foreseeable future.

Ben Young

President,
European Medical Writers Association

UK MEDICAL WRITERS NETWORKING GROUP

You may remember in the last issue of the EMWA newsletter there was an article by Julia Spivack (Hoechst Roussel) calling all UK medical writers regarding the iniation of a UK Medical Writers Networking Group and there was a meeting scheduled at the Berlin conference for the UK delegates to discuss this issue. At this meeting the unanimous feeling was that this would be unnecessary duplication of the work of EMWA. Many of the ideas for a UK association (for example a database of freelancers, involving personnel departments, medical writing recruitment advertising, workshops in the UK) were already being discussed an realised by EMWA. A number of individuals commented that this meeting felt like the beginning of the formation of EMWA. The outcome was that any innovations for the UK would be best realised at the European level. However if there is a desire for UK medical writers to meet up informally from time to time give your suggestions to Julia Spivack on 01908 680460.

CLARIFYING THE EC REGISTRATION GUIDELINES

Most of us in the pharmaceutical industry have experienced the frustration of working with the guidelines in the EC Notice to Applicants for preparing clinical dossiers for registration submission. The guidelines are notoriously vague and can be interpreted in a number of quite different ways. Because companies do not generally make their registration dossiers available to the public, those of us who are employed by individual companies usually are only familiar with a single, in-house interpretation. Freelancers are not much better off, since companies rarely send such important projects out. Recently, I was able to see a Clinical Expert Report from a different company and was surprised to see how much the structure differed from the ones I had prepared.

I was discussing this issue with Ben Young and we realized that there might be considerable interest among European medical writers regarding the different approaches to structuring a clinical dossier, especially since the new European Community Notice to Applicants will soon be issued with a new and poorly defined mandatory requirement, the Written Summary. Thus, the organizers of the annual EMWA meeting in Berlin decided on a two-pronged approach to try and clarify the registration guidelines. First, Dr David Jeffreys, of the Medicines Control Agency, UK, was invited to present the Keynote Address: **The Enhanced Role of the Medical Writer in the New European Drug Registration Process** so that we could both hear his views on the interpretation of the guidelines and ask him questions regarding our specific problems. Second, a panel discussion was set up to provide a forum for the exchange of views among the people who have actually prepared clinical dossiers: medical writers and drug regulatory affairs representatives. The panel consisted of the following people:

Barry Drees,
(Chairman), Medical Writer, Hoechst AG, Germany.
Art Gertel,
Director of Medical Communications, Schering-Plough, USA
Rosemary Bischoff, Head of Clinical Support Services, SBU Therapeutics, Schering AG, Germany
Rainer Dorow, International Project Management, Schering AG, Germany
Garth McBride, Head of Regulatory Affairs, Schering AG, Germany
Barrie Willet, Head of Translations, Schering AG, Germany

David Jeffreys discussed the preparation and structure of the clinical dossier with particular emphasis on the Clinical Expert Report (CER) and the Written Summary (WS). I have heard him speak about CERs several times over the years, and clearly experience has tempered some of his views. For example, he now recognizes that it is practically impossible to begin writing the CER when clinical development begins, as he recommends, as well to use an outside expert as the author of the CER. Because the expert needs long-term and detailed knowledge of the drug development, it is only reasonable that the expert will have to be from inside the company except for only very small or specialized submissions. Many of the CERs he has seen have been signed by company experts, and it seems likely that this trend will continue, if not increase.

David Jeffreys' presentation stressed several main points, but underlying all of

them was the often unappreciated difference between data and information. The key to a good dossier is not simply to provide masses of data, but to provide the information to make that data comprehensible. Every effort should be made to make the dossier user-friendly. This should include, but certainly not be limited to, navigational aids (clear instructions in a prominent place as to the structure of the dossier and the location of its various parts); a clear, logical, consistent and complete system of cross-referencing; and intelligent selection of the data to be presented (data vs. information).

In discussing the CER, he stressed that writing it should be a process, begun when clinical development starts, and not something thrown together at the end of clinical development. Thus it should present the historical development and justify the decisions made (this point is frequently ignored). The function of the CER is to take and defend a position about the drug, not simply summarize the dossier. Previously, these two functions could be combined in the CER, as long as one kept to the maximum of 25 pages, but according to the new guidelines, the clinical data supporting the submission is now to be submitted in a new document called the Written Summary.

As most people are probably now aware, the biggest change in the guidelines is that a written summary of the dossier is now mandatory. Dr. Jeffreys stated that the written summary should be a factual summary of the registration dossier (leaving the discussion for the CER). It should not duplicate other parts of the dossier and therefore, he emphasized that it definitely should not simply consist of short, study-by-study summaries, since this information is already attached to the CER in the form of the study synopses. He noted that it could be multi-format, i.e. combine text and tables, which should finally lay to rest the common reaction that a "Written Summary" can contain only text and no tables. I asked what should be done with certain tables which summarize or pool data for the dossier and are very long (sometimes longer than 30 pages) and yet must be submitted, since they do not appear in any of the individual study reports. He suggested that they could be included as an appendix to the written summary. This would imply that the massive tabular presentations which many companies have submitted in the past (sometimes referred to as Overall Summaries) could become Written Summaries with the important summarizing tables presented as the Written Summary itself, and the longer tabular listings as an appendix.

The panel discussion was intended to address some of the more specific questions than would be appropriate for Dr. Jeffreys. Of particular interest was Art Gertel's experience since he claims that his company prepares global dossiers for both the FDA and the European authorities, something most people with experience insist cannot be done. The resolution of this apparent conundrum is about what one would expect - study reports and some summary tables are prepared for both dossiers with modular add-ons for each of the two separate authorities. Clearly, documents such as the Integrated Summary of Safety (for FDA) and the CER (for Europe) must be prepared individually for the respective authorities.

Everyone on the panel agreed that navigational aids to the structure of the dossier were extremely important. Art Gertel tries to ensure that the person who delivers the dossier to the relevant authorities identifies to them at the time of delivery exactly where the navigational aid can be found. Schering

includes a copy in every individual volume of the dossier so that it is available for easy reference to any reviewer. This problem should, in the future, be greatly reduced with the increasing use of electronic submissions which are designed for ease of navigation.

The panel felt it was necessary to submit all additional adverse event information (our Adverse Event Review) in a unified document with some sort of message and not to simply include it haphazardly (information vs. data). At Hoechst, we compare all adverse event data being submitted (registration studies) with all other known data (studies not yet completed, Japanese data, post-marketing data in other indications, etc.) with a view to showing that the studies being submitted are truly representative of the known safety profile. Although everyone agreed that this was a desirable goal, it seemed clear that for some companies, reality did not always reflect the ideal.

There was also general agreement that all summary documentation should be self-contained, i.e. direct reference to study reports for information necessary to understand points made in the CER should be avoided. Critical tables or figures from key studies can be reproduced in the CER if necessary. This is of particular relevance for clinical pharmacology where there may be only a single study to support some claims and may become even more important if the drive to streamline early Phase I development bears any fruit. On the other hand, there were different approaches to presenting the summary data tables with some people referencing them directly in the CER and others selecting the most important parts for direct inclusion in the CER, leaving the remaining data tables as an appendix (see discussion of Overall Summaries above). Subgroup analyses are handled similarly by everyone, with a short summarizing text included in the CER and reference to a much longer separate document which includes a more detailed discussion and all the supporting data tables.

Unfortunately, the panel discussion was only planned for one hour, and there were a number of issues I would have liked to bring up but could not due to the limited time available: literature references in the CER, format of the Written Summary, structure of the Overall Summary of Clinical Pharmacology, etc., but everyone attending agreed that we should do something similar at the next EMWA meeting, perhaps with more time. If anyone has any questions or problems they would like addressed next year, please contact Barry at:

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WHAT HAVE YOU HEARD?

If you have attended or will attend any meetings or conferences where subjects of potential interest to our members are discussed, become an "EMWA roving reporter" and let us know about it. Any aspect of current or future pharmaceutical legislation or practice, licensing or reporting - send it in. This especially applies to AMWA 1996 at Chicago.

You do not need to express an opinion, though it may be more interesting if you do, and of course, to protect the innocent, names can be kept confidential....

6th INTERNATIONAL EMWA CONFERENCE - Edinburgh, May 14-16, 1997.

From the Conference Manager:

Hi folks,

The haggis is being chased, the whiskey is being distilled, the salmon are biting the hook and John Aitken is rubbing his hands in glee at the prospect of charging reasonable (?) fees for lessons in how to understand the Scots when they try to speak English.

We have picked a superb hotel - the CARLTON HIGHLAND HOTEL which is situated on North Bridge right in the very heart of the historic part of the city, overlooking the river and only a few minutes walk from the famous Edinburgh Castle. There's also the train station and the main shopping areas right on the doorstep.

If you are too scared to go "ootside", the Carlton Highland Hotel boasts a comprehensive sports and leisure club comprising indoor swimming pool, gymnasium, Turkish bath, solaria, saunas and squash courts. There is also a hairdressing salon, nightclub, giftshop and three restaurants within the hotel.

Social programme:

However, we have three irresistible social events to lure you out. On Wednesday evening there's the main conference banquet - a once-in-a-lifetime opportunity which is not to be missed (Aitken buying a round? - Ed.) at the 700 year-old Dalhousie Castle. There will be a five course banquet with lots of wine and whiskey and a great opportunity to take photos of your colleagues making a real fool of themselves to send to their manager (or the Newsletter- Ed.) before their next performance appraisal.

On the Thursday evening we offer you a choice of two of the very best ways to spend an evening in Edinburgh:

A rare opportunity to taste the fine malt whiskeys of Scotland, including a sumptuous banquet at the Scotch Malt Whisky Society.... or,

A spooky "ghost tour" of medieval Edinburgh with gruesome tales, followed by first class cuisine in a unique atmosphere at "The Witchery by the Castle".

Workshops

Eight workshops will be offer and we have planned to include:

3 required AMWA core courses

3 elective AMWA core courses - 2 of which will be brand new courses never touched by the human neurone!

2 advanced AMWA core courses

Sponsorship

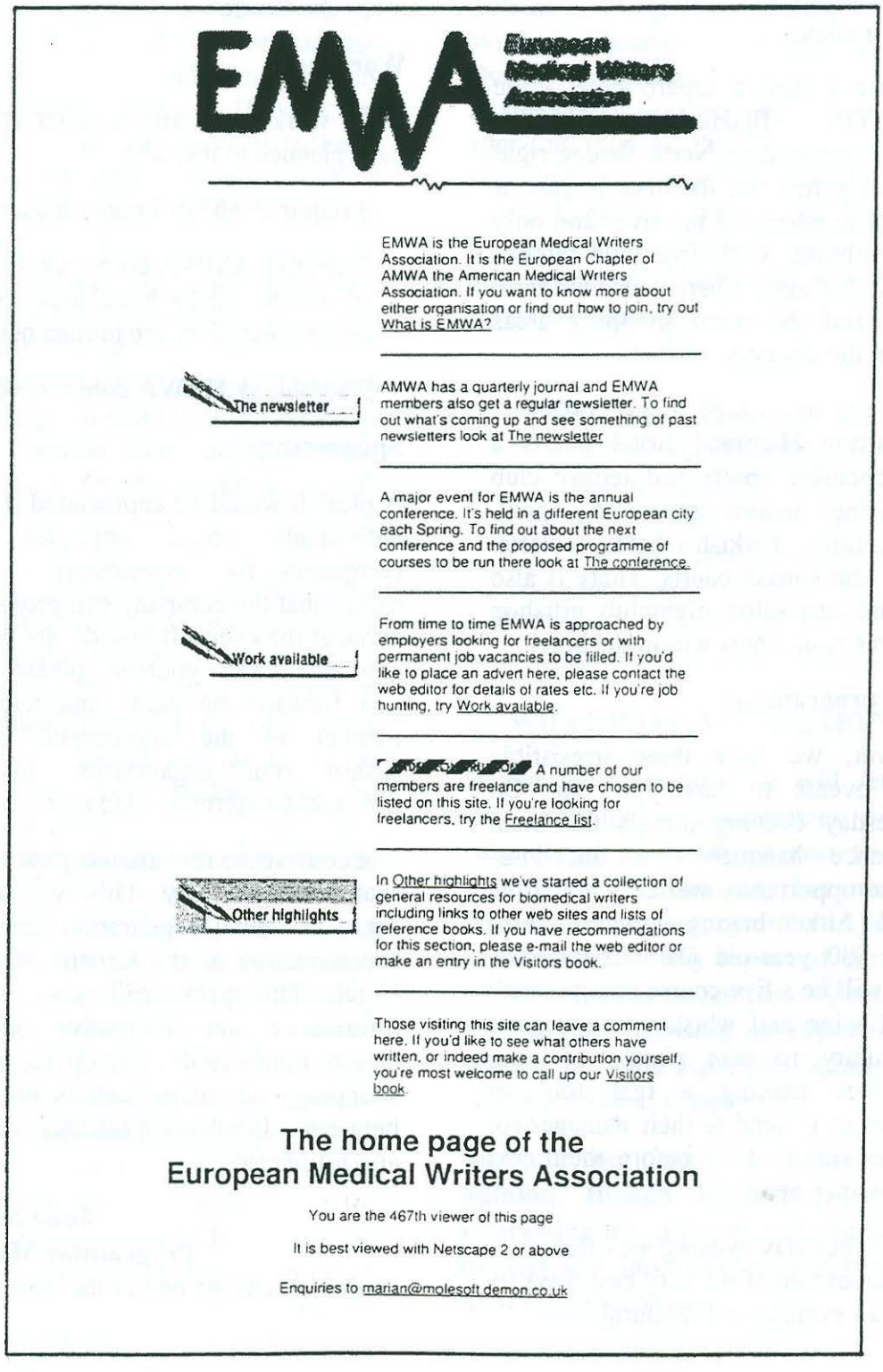
A plea! It would be appreciated if a few individuals could approach their companies for sponsorship - which means that the company can promote its name at the event. If you do not wish to approach them yourself please could you forward the name and telephone number of the appropriate contact within your organisation to Julia Spivack, Conference Manager.

The conference registration pack will be sent out in January. This will include details of final registration costs and accomodation at the Carlton Highland Hotel. The pack will also contain information on alternative accomodation, things to do, e.g. opera, theatre, shopping, etc. maps, details of flights between London/continental Europe and Edinburgh.

Julia Spivack
Programme Manager
(Address at the end of the Newsletter)

Surf's up at the EMWA World Wide Web site!

Below is a representation of the EMWA Home page on the World Wide Web (which fails to do it justice), expertly prepared by Marion Hodges. If you want to know more point your browser at **http://www.netlink.co.uk/users/emwa/** and surf on over, or send your comments to **marion@molesoft.demon.co.uk**.



Dear Maeve,

EMWA is delighted to announce that the world renowned agony aunt, Maeve E. Cummin, has agreed to answer your questions and problems in our newsletter. So if you have any problems, technical or personal, please send them in to us and we will ensure that Maeve gives you the benefit of her wide experience. Just by chance we had already received some queries from members which we were able to pass on to Maeve for her inaugural column.

Dear Maeve,

My new whizz-kid boss keeps going through my work taking out half of the spaces. This has never happened to me before in 40 years of loyal service.

Gladys Emmanuel.

Dear Gladys,
Don't worry dear, this is just technology catching up with you. Like everyone who learned to type on a typewriter, you are still putting two spaces after a full-stop. The thing is, these new-fangled food-processors already know to put larger spaces after a full-stop, so you only need to put one. Still, I bet we could still teach this Johnny-come-lately a thing or two about writing, eh?

Maeve

Dear Maeve,

I am a healthy guy with a wide range of interests but I have a terrible problem. Whenever I have been working until all hours, hunched over my document, I get the irresistible urge to use a pair of curling tongs. As you can imagine, this is proving very embarrassing. Please help.

Curly Oates

Dear Curly,
Don't worry dear, you are perfectly normal. What you are suffering from is a well-known condition - writer's crimp. This is brought on by the intense concentration on the document in hand, and in the bottom drawer of many a writer's desk, hidden beneath the piles of dried-up pens, half-eaten chocolate bars and those references you keep meaning to read, you will find a pair of curling tongs.

This condition often alternates with that other rarely discussed, but all too common condition - writer's clock. This is characterised by such a compulsion to constantly check on the time that it dries up all other thought processes in your brain. Each time a creative idea tickles the edges of your mind, your eyes are drawn to your wrist-watch or wall-clock. After a while your mind becomes a complete blank and the only thing that gets you through to your next glance, is ticking off the seconds in your head.

Like many common afflictions, there is no known cure for either of these conditions. The only thing known to help is to get outside, feel the sun on your pallid skin, get high on non-recycled oxygen and feel a breeze on your cheeks that does not originate in the labyrinth of air-conditioning ducts.

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* For information on membership or application for membership in EMWA please contact the secretary at the above address.

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