The Write Stuff

The Journal of the European Medical Writers Association

Past, Present, and Future

Featuring:

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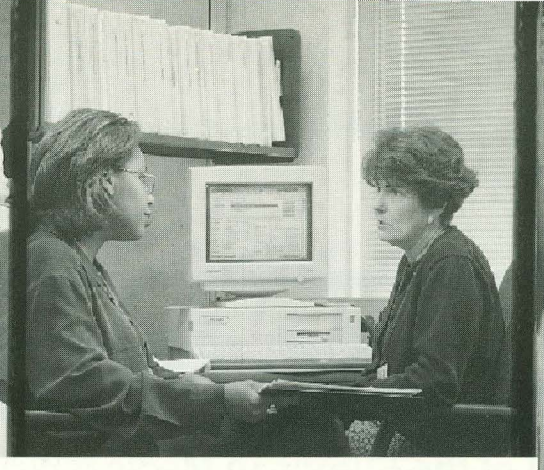
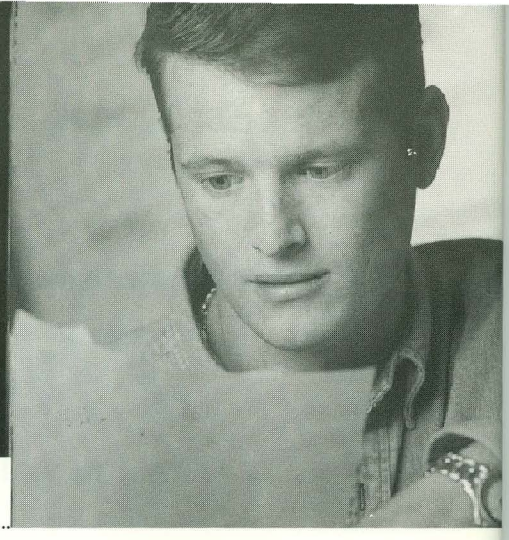
EMWA European Medical Writers Association

Winter 1998/99

Vol 8, No.1





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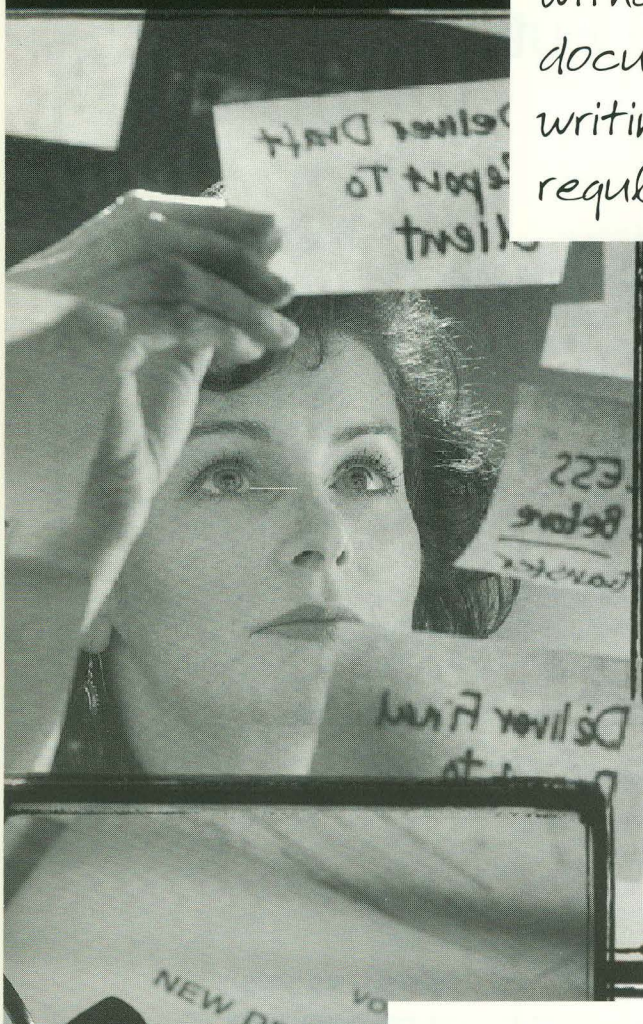

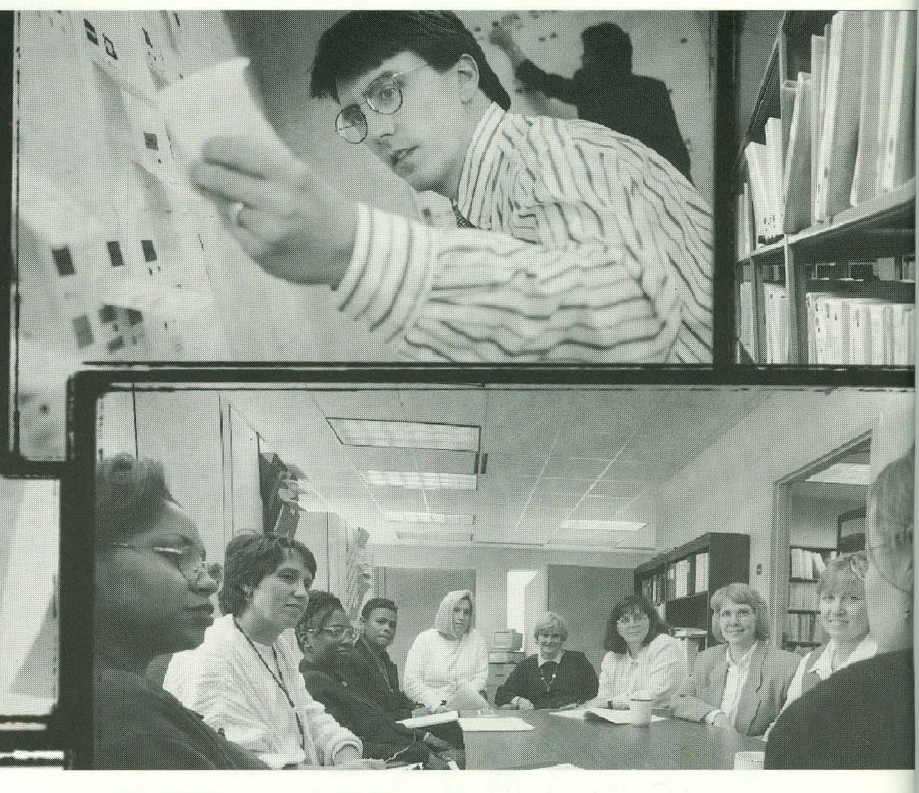

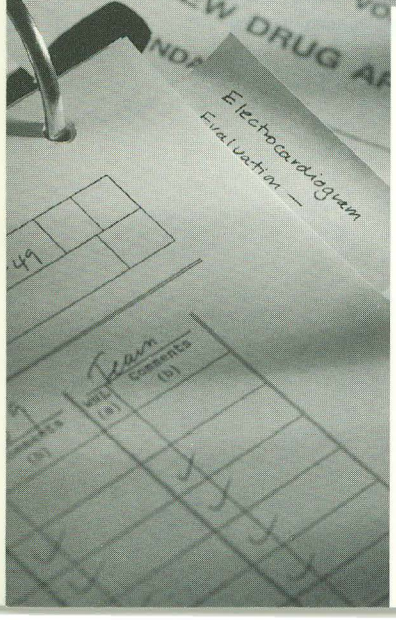

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Past, Present, and Future Issue (Winter 98/99)

Features

Regular Columns

[INT] This symbol indicates that the article also has been or will be published at the EMWA internet site: 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:

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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 cleared 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...

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Liz Wager

The Editor's Red Pencil

by Barry Drees

Greetings fellow members,

Some of the more perceptive of you may have noticed that I attempt to present a theme in each issue (and no, the theme of the first issue was not "Copyediting is important"). This issue takes a look at the changing nature of our profession, both medical writing itself and the medical profession with which we are so closely associated, and thus I've called it the "Past, Present, and Future" issue. Of course, you can look forward to articles about change in the profession for the foreseeable future as we are privileged to be members of a profession which, while perhaps no longer in its infancy, can certainly be said to be in its adolescence in this time of mergers and restructuring.

When I first agreed to be editor and began thinking about what kinds of articles we could present, it occurred to me that one topic that would be good would be that of "alternative medicine" which seems to be quite current as well as controversial (the two things an editor loves). In fact, I was beaten to the mark by our colleagues down under who dedicated a recent issue of the **AuMWA Journal** to alternative medicine. I was particularly intrigued by the several stormy letters to the editor that were published in the following issue, criticising the lack of objectivity. Aah, hindsight is golden, and I hope we've avoided that problem, but please don't hesitate to write to me if you don't agree or if you have any other comments about these articles. There's nothing I'd like better than to publish a few irate (or otherwise) articles from the membership.

Medical writers don't seem to be involved in alternative medicine much, but as it gains acceptance and visibility, we may find ourselves writing about it in the future. Because alternative medicine tends to take an individual and holistic approach, it hasn't lent itself to being tested by controlled clinical trials. This could provide unique opportunities, both for practitioners to investigate its effectiveness and for medical communicators such as ourselves to describe the findings.

Finally, I just heard that one of our members is moving to Iceland where she will continue her career. Well, now we can truly say that the sun never sets on the EMWA empire (at least not in the summer). I was really excited to hear this as editor, however, since it means that we can finally round out our geographical diversity series with a "View from the North"! Stay tuned.

Barry Drees

From the President's Desk

by Gerold Wilson

Dear Fellow EMWA members,

As I reported in the last issue of *The Write Stuff*, incorporation has now taken place. EMWA is now a non-profit organisation under the laws of the United Kingdom. I and the other members of the EC are pleased that this long-term goal has been realised and we hope that you share our enthusiasm. We will discuss incorporation at the General Business Meeting that will be held at the Copenhagen conference, and we will ask the membership to approve the Articles of Incorporation. I will see to it that a copy of the Articles are sent out in a mailing with the next issue of *The Write Stuff* (or in a separate mailing, if this is not feasible).

At the EC meeting near Heathrow on 17 November 1998, the following issues were addressed:

While I attended the Vancouver conference, Barbara Good (AMWA President), Art Gertel (AMWA Immediate Past President) and I talked about EMWA's affiliate status and the financial aspects of our relationship with AMWA. The EC will need to submit a statement of affiliation to AMWA before the AMWA Board Meeting in April, but the gist of the agreement is that we no longer will pay a portion of our annual membership dues to AMWA and will pay the AMWA chapter rate for Core Curriculum and Advanced workshops in the future, rather than the $5.00 more per head that we have been paying. The EC and I agree that an EMWA/AMWA affiliation on the basis of such an agreement will mutually benefit both organisations and it is an agreement that we can live with for a long time.

The EC has firm plans to initiate the Corporate Sponsorship Programme in February 1999 with a mailing to all pharmaceutical companies and CROs. Jane Stock is working on the final wording of our letter and I am contacting EMWA members across Europe to establish exactly to whom we need to send the letters. If any of you have ideas regarding who we can contact to elicit support, please send an e-mail to me (gerold.wilson@schering.de). Most of you know my views on the importance of corporate support of our efforts: significant funding will enable us to extend the scope of our educational work (i.e., a second "session" of workshops per year) and will help us decrease the cost of conferences (and workshops) for members. I feel confident that we will meet the February 1999 deadline and I hope that we can report our first successes at the Copenhagen conference.

I have asked Barbara Grossman (Treasurer) to start planning for a 1-2 day workshop session to be held in the latter months of 1999. The EC sees this as a low-cost, workshop-only event to increase continuing education opportunities. The session, if we can get it going, will probably be held in England, near London Heathrow Airport. If you have suggestions or would like to lead a workshop session, please get in touch with Barbara or Julia Cooper.

And now I'd like to introduce a special message from our current Vice-President and future President, Geoff Hall:

In his speech at the Madrid 1998 conference, new President Gerold Wilson set as one of the objectives of his year in office the establishment of EMWA as a legal entity. Up until this year, EMWA has been a loose club with a constitution of sorts, but with no legal identity. This caused problems, not least with banking. The EMWA bank account for several years had to be a personal account of the treasurer. The implications of this could have been disastrous. Thankfully (not just for this reason. We would seriously miss him), Philip Cooper did not fall under a Basel bus during this period.

So what has changed? EMWA is now a limited company. The type of company that has been formed is called a company limited by guarantee. This means that there are no shareholders as such and so no-one has to fork out for their shares. However, every member of EMWA is now a member of the company. (Remember to make sure you are paid up.) EMWA cannot pay dividends to members and no-one can profit from the company. The company can make money from bank investments without any individual such as the treasurer being liable for the tax.

As a corporate body, we have more standing when it comes to discussions and negotiations with other bodies such as government, educational or EU bodies. By establishing EMWA as an 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 Incorporation, is legally binding. We have to stick to rules. The general business meeting at the conference becomes the annual general meeting (AGM) of the company and is sovereign. The committee are the board of directors of the company and responsible to the AGM.

Is there a downside? If a company limited by guarantee goes bust, each member is liable for outstanding debts up to a personal liability of a staggering £1 (yes, one whole English pound). Oh and also on the downside, but only for me, it was a pretty tedious job to get it set up.

So what next? The invitation to the Copenhagen conference will include notice of the AGM of the company. Among other business and elections, members will be asked to ratify the formation of EMWA as:

The European Medical Writers Association
A company limited by guarantee

If anyone would like more information on all this (serious requests only please because it will involve a ton of paper), contact Geoff Hall (see back cover for address).

Traditional Medicine and Healers in South Africa

by Daleen Krige

With the many changes in South Africa and a renewed challenge to provide accessible primary health care to all, the role of traditional medicine has once again moved into the spotlight. A traditional healer can be described as follows: "Someone who is recognised by the community in which he lives as competent to provide health care by using vegetable, animal and mineral substances and certain other methods based on the social, cultural and religious background as well as the prevailing knowledge, attitudes and beliefs regarding physical, mental and social well-being and the causation of disease and disability in the community".[3]

The two main kinds of traditional healer are the *diviner* and the *herbalist.* Traditional healers are not witchdoctors (*izangoma, Zulu word for "witchdoctor").* Diviners use listening, observation and experience to make a diagnosis aided by the supernatural (communication with ancestors) and the throwing of bones. A person normally does not choose to become a diviner, but rather follows a calling (*thwasa*), which can be disobeyed only at risk of serious (sometimes fatal) illness. An apprentice (*ngaka*) undergoes an apprenticeship of up to seven years with a fully qualified diviner. Only after a ceremonial ritual and a test of the person's abilities can they start practising as a qualified diviner. Sometimes the diviner also trains as a herbalist (*inyanga* [Zulu] *or ixhwele* [Xhosa]*)* and can practise both healing vocations simultaneously or separately. The herbalist acts as a druggist, dispensing medicines (*muti*) made from natural substances including bark, roots, leaves, animal skin, blood or parts of animals, herbs, or seawater.

To understand traditional African medicine, it is important to understand the life and world views of the traditional Africans. According to Wessels: "The world views of traditional Africans are not integrated but form a complex system in which beliefs concerning ancestral spirits, magic, sorcery, witches and pollution exist together. This loose association provides a natural way of understanding misfortune and provides understandable answers to the vexing questions of the purpose of life".[4] To the traditional African, health thus means to be in harmony with cosmic vitality/energy (e.g. ancestors are involved in the lives of the living and have to be honoured, otherwise they can cause ill-fortune).

Therefore, in the African view, causation of illness is regarded as: natural (accidental or congenital, e.g. mumps, porphyria), animistic (influence of wind, clouds, earth, water on people, e.g. colds, rheumatism), magical (sorcery, witchcraft, e.g. insanity, headache), or neglect of paying homage to ancestral spirits (e.g. misfortune). These examples can vary considerably, due to differences between cultural groups.

Treatment therefore involves restoring harmony within the body as well as between the body and the cosmos. Medicine also needs to have a strong symbolic meaning, e.g. the belief that white medicine protects against sorcery and red medicine cleanses the blood. It is also believed that characteristics of an animal/plant are transmitted to the user: e.g. the Tswana would use crocodile skin for fever since the crocodile, being a water creature, symbolises cooling-off, or the Zulu would use lion or elephant (or any strong/fierce animal) parts as a potion against anxiety. Diviners will prescribe the wearing of an armlet or necklace, made of animal skin, as a protective amulet against evil or illness.

The Tswana would use crocodile skin for fever since the crocodile, being a water creature, symbolises cooling-off.

These medicines are administered in a variety of ways: orally as a liquid (e.g. plant juices or tea from dried plant parts), as a powder/paste (either orally or as an ointment), as a washing solution (in a bath - the healers would often bathe the patient themselves, outside their house, using specially prepared bathwater), applied as inoculations, as inhalations (as a snuff or boiled in water with inhalation of the vapours) or as smoking agents. A steambath is usually used to remove harmful "medicine". Hot liquids are also often sucked from the fingertips to ward off evil or danger. Ground medicines are often administered rectally. In order of popularity, the treatment methods normally employed include: induction of vomiting, administration of an enema, inhalation (either as a powder or vapour), and incisions in the skin with the rubbing of medicines into the incisions. Almost any plant part as well as whole plants are used as the basis from which to prepare medicines.

Here are a few examples of applications of traditional medicines for various ailments, as used by the South Sotho[1]:

Ailment	Treatment
Diarrhoea	• Roots of the *mosokelo* plant are dried and boiled in water. The liquid is taken orally 3x per day.
Stomach ache	• Roots of the *sekatapohwana* plant dried, pounded and boiled in water. • Potassium permanganate dissolved in water. • A drop of seawater added to drinking water. • *leshogwa* leaves, dried, pounded, bottled in lukewarm water, and left for a day before use.
Heartburn and gall	• Seawater as vomiting agent. • Holy water (from a diviner) as vomiting agent.
Nausea and vomiting	• The inside of a chicken's breast, dried and milled. A pinch of the powder is taken in half a cup of water. • A bit of dried pomegranate skin in water taken after each bout of vomiting

Traditional remedies, particularly those involving plant products, are like many pharmaceutical industry products and thus may have associated side effects. It is known amongst herbalists that the toxicity of plants can vary with the season (which may be one reason for low-dosage forms of traditional medicines). Preparation processes are important to toxicity as some (like heating) may eliminate some toxins, but increase toxicity via a chemical change brought about by heating. Research and knowledge of the pharmacologically active compounds in traditional treatments can make a great contribution towards making the methods more systematic and reliable.

Cases of toxicity are especially common in children, when dosage is incorrectly determined. Mortality is often high in such cases as even if the help of a western doctor or health worker is sought, the details of the toxicity are not fully related, either through neglect or ignorance. Such cases are sometimes not even recorded, as the African world view allows for infant deaths as purely the will of the ancestors, and even when they are reported, they are not attributed to traditional medicine because "herbal intoxications are not considered to be an unnatural cause of death"[5] and post-mortems are often not performed. These are all contributing factors to the inadequate knowledge of the properties and toxicity of traditional medicines.

When the incorporation/toleration of traditional healers and methods into the western system are discussed, there are 4 basic models:

- **Exclusive system**: Only western medicine is practised with the total exclusion of any form of traditional medicine. This is probably impractical, as people will use traditional medicine anyway.

- **Tolerance system**: Only western medicine is officially practised, but traditional medicine is not prosecuted. This is currently South African policy.

- **Inclusive system**: Both systems are accepted and exist completely independently of each other. This is the easiest system to implement.

- **Integrated system**: Both systems are merged into a new system that combines the best of both systems.

Since the Alma Ata conference in 1978, there has been increased support for either an inclusive or integrated system. When comparing traditional medicine practices to western uses, it is clear that there are certain areas where the one can be of service to the other. If the traditional healer can be utilised by western medicine in anti-AIDS campaigns or tuberculosis awareness programmes, for example, everyone will gain.

The fact that there are many more traditional healers than western doctors make them valuable health workers within the community; in some areas the ratio can be as high as two thousand to one[3]. It was estimated in 1986 that there were about 100,000 traditional healers in South Africa, as opposed to 20,200 registered medical doctors[2]. The advantage of the traditional healers lies in the fact that they know the cultural

traditions and they have more time to pay attention to the patient's ailments. This way, accessible primary health care within communities can be established, provided that the healers are given the necessary training.

There is a movement towards recognition for traditional healers and their services. According to Evelyn Levitz: "The traditional healer should be formally and legally recognised as a health care resource, but one that operates within totally different paradigms, each with its own code of ethics and criteria. The traditional and western health care services would (then) run parallel to each other with mutual recognition of the services each can provide"[2]. This trend towards recognition is manifested in the formation of two organisations where they may affiliate: the South African Traditional Healers Council (SATHC) and the African National Healers Association (ANHA). Affiliation is not yet compulsory. There is also talk of including a course in traditional healing into the syllabi for medical students to increase awareness and understanding of traditional practices. This has been done by the University of the Witwatersrand. It may also result in a more scientific approach towards dosage.

Generally speaking, there is greater acceptance of traditional practices, and more people realise that both systems have valuable contributions to offer in the quest for health.

Generally speaking, there is greater acceptance of traditional practices, and more people realise that both systems have valuable contributions to offer in the quest for health. Traditional healing and medicines existed in South Africa long before western medicine arrived, and will no doubt continue to exist in the future. If a system can be devised that allows the cultural expression of traditional medicine combined with the scientific advantages of western medicine, both types of healing can profit and the community will reap the benefits of an improved health system.

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Alternative Medicine in Germany

by Anna Kassnel

Most people don't know much about natural healing until they turn to it when conventional medicine fails. In Germany there is an officially recognized profession of "natural healing", the so-called Natural Healing Practitioner or Heilpraktiker (HP). Somewhat surprisingly, it was not until 1939 that a law on natural healing was enacted. Before that, Germany allowed anyone to practise their own system. This led to an open market for quacks and other charlatans with considerable abuse of an ignorant populace. The problem was finally addressed with the HP law in 1939, where admission to the profession was regulated, and limits to what could be practised were defined by general regulations, both for natural healers and for practitioners in the public health system.

Today, the training in natural healing takes about 2-3 years, depending on the institution, and it is not funded by the state. Usually, the education consists of individual training modules with the actual programme chosen according to individual preference, either as full-time study, intensive course, evening classes and/or weekend training. In addition to basic medical knowledge in subjects such as physiology and pathology, the study programme focuses on physical examination and diagnostic methods and is part of a core curriculum which is tested by exam. More specific techniques are optional, although students tend to choose one or more (see below). Most training stresses practical experience with the various techniques. Certification requires the completion of a state examination (held twice yearly).

The HP, like an MD, follows the basic principles of "do no harm" and, of course, "who heals is right". However, because natural healing is done on an individual basis and is by its very nature holistic, i.e. frequently involves a combination of methods, it is not amenable to testing by controlled, clinical trials. Evidence for its efficacy is primarily anecdotal and such evidence is often not accepted by the scientific establishment. Nevertheless, certain aspects, especially the emphasis on a healthy lifestyle and proper nutrition, are shared with evidence-based medicine.

Alternative medicine follows the basic principles of "do no harm" and "who heals is right".

As most health insurance schemes do not support "unscientific" treatments and only a few selected "natural treatments" are recognized, patients do not usually receive reimbursement for treatment by an HP. As one can imagine, an HP therefore needs a very good reputation to maintain a viable practice. Since advertising is strictly regulated (for example, announcements in local newspapers are allowed only when a new practice is opened and then only for 5 consecutive issues or different newspapers/magazines), many HPs give local educational presentations on natural healing topics.

Some of the more commonly encountered forms of natural healing in Germany include:

Homoeopathy: Developed by Samuel Hahnemann (born 1755 in Meißen/Germany). Based on the premise that the symptoms of a disease are a manifestation of the body's natural defenses. By treating a disease with vanishingly small amounts of a substance that in healthy people produces symptoms similar to those of the disease being treated, it seeks to stimulate the body's natural immune system. Somewhat paradoxically, remedies gain potency by dilution. This system gained notoriety in the late 1980s when a French researcher, Jacques Benveniste (INSERM 200 Institute, Paris), attempted to publish "scientific" tests of the principles in the journal "Nature". Practitioners claim that homoeopathic remedies don't have any side effects; sceptics claim that this is because there is nothing in them.

Kinesiology: The so-called "science of movement". "Applied kinesiology" was founded in 1964 by the American chiropractor, George Goodheart, and uses "manual muscle testing" to find imbalances, tension, and blockage in the body. The kinesiologist then rebalances the nervous system, finally retesting to verify that a change has taken place.

Phytotherapy: A very ancient method of healing (also used by some ape species) and not different in principle from the pharmaceutical industry. It uses plants and plant extracts for healing and alleviation of symptoms.

Acupuncture: A method originating in China where needles (with applied heat or electrical stimulation) are inserted at very precise points to encourage the body to promote natural healing and improve functioning.

Bach flower remedies: A system developed by Dr. Edward Bach in the 1930s in the UK. Although, with its very small amounts of active ingredients, it is superficially similar to homoeopathy, the basic philosophy and method of preparation are very different in that Bach flowers are given according to emotions and personality types determined by the practitioner.

Reflexology: 'Reflex' zones are skin areas that direct an impulse (as in massage) to certain organs in the body. Foot reflexology is the most common technique used.

Iris diagnosis: A diagnostic procedure used to elucidate the complex of reasons for an illness based on the idea that each organ or part of the body during illness is reflected in a certain part of the iris – the so-called projection field (sector).

Regular subject-specific training and refresher courses are mandatory for the HP and start during the educational period. Continued updates are also possible through national HP congresses every year, where information and treatment experiences are shared and the latest products and therapy tools are presented. In addition, there are many smaller, organized symposia where individual subjects are presented both for HPs and other health professionals. Sharing of information between the HP and established medical communities is increasing and suggests that the two can learn from each other to improve the health of the population.

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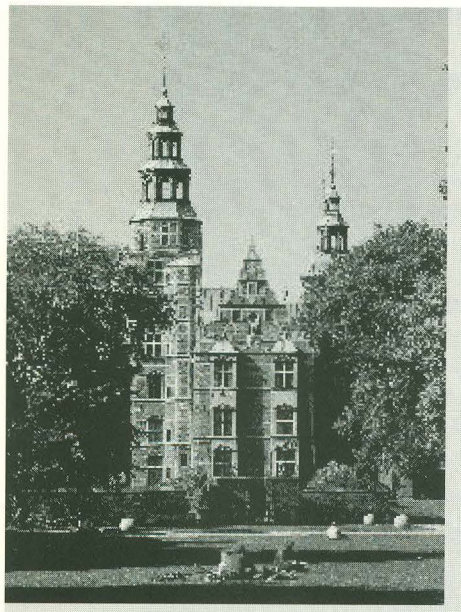

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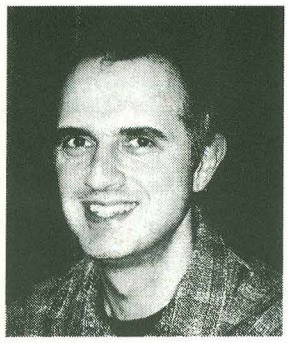

View from the Past

by Mike Matthews

I still maintain that I was the one who started EMWA one day by lifting the phone and calling round every European drug company I could think of until I found some other medical writers. It was 1986 and I had just returned from my first AMWA meeting in San Francisco. I was weary of feeling like a curiosity in my working environment and energised by the richness of the AMWA experience, even though my workshop exercise on audio-visual presentations had been comprehensively rubbished by the rest of the workshop attendees - fair enough, because they knew what they were talking about whereas I was taking a bold stab at the exotic.

Stephen de Looze and I recognised each other's European accents among the 400 or so American ones during the meeting and got together back home afterwards. We were both working for big companies at the time (Stephen still is) and sponsorship for an AMWA meeting was not a problem. It could be sensibly tied in with a visit to the US on company business. I will be forever grateful to ICI, my then employer, for sending me to San Francisco. That first AMWA meeting confirmed my choice of career as valid, full of potential and absolutely right for me.

But when I got home I was still alone, professionally speaking. So I got on the phone. The first meeting of about half a dozen European medical writers was held at ICI Alderley Park, UK, and the invitees included myself and Jane Mitchell (both then of ICI), Brenda Moore (then of Glaxo), Linda Dearden (then of Boots), Stephen de Looze (Hoechst), and delegates (as far as I remember) from Fisons and Janssen. We were all mainstream bread-and-butter industry writers. I doubt whether any of us knew much about the rest of the profession at the time.

It was a modest affair alright, but it was the true beginning, oh my children, of the thriving organisation that is EMWA today. The following year I talked Fisons into hosting a meeting of about a dozen delegates in the UK, and the year after I was proud to be a non-UK delegate from my new job with Sanofi in France to make the opening remarks at the first truly international meeting, hosted by SmithKline Beecham in Brussels. The long-running discussion about how (and indeed whether) EMWA should be associated with AMWA started then. It completely polarised the group. One writer berated us for railroading through a motion in support of the link and swore (as I remember) never to set foot ever again, etc. etc. etc.. He got over it, though. I saw him in Madrid at the 1998 meeting.

It's a great boost to feel that you belong to a group of like-minded people (however eccentric).

Indeed, many of the originals are still coming to EMWA meetings. After several more company-sponsored AMWA and EMWA meetings, I missed a few (I was a busy but parsimonious freelancer for four years) but I got back into the loop at the Edinburgh meeting in '97 and also made it to Madrid in '98. What struck me most on my return to EMWA was that the new writers I met at these meetings were saying exactly the same things I had been saying of AMWA in 1986: firstly it's a great boost to feel that you belong to a group of like-minded people (however eccentric) and secondly it's a great benefit to learn from the more experienced among them.

Nowadays, European medical writers take it for granted that all of this exists relatively close to home. That is very important. AMWA was the model for EMWA, particularly in its provision of training workshops, and we should never forget that, but AMWA cannot provide for the needs of those European writers who do not benefit from big-company sponsorship for trips to the US. And any professional organisation needs the diversity of experience and view that comes from having members from across the whole spectrum of its activity, not just the heavywieghts or the big-company people.

Having grown from parochial beginnings, but with links to the US through AMWA, we are now also the home organisation for writers from far north, south, east and west of Europe, which is how this series of "View From..." articles got started, and we Europe-based members benefit from this source of diversity of experience too. But what about the fourth dimension: time? The view from the past is special. It belongs to but few of us. The view from the future is going to be better still. It belongs to us all.

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Department of Corrections – Autumn 1998

1. **The e-mail address for the Freelance Opportunity was given incorrectly. The correct address is:**
   Monique@luz.com
   See corrected advertisement on page 23 this issue for complete address.

2. **The *AMWA Journal* reference for Robert J Bonk's article, "Reversing the Report-Production Process When Teaching Pharmaceutical Writing" was deleted from the final copy. It is as follows:**
   AMWA Journal, 1998; 13 (1) 17-19.

The Future of Medical and Technical Writing

by Stephen de Looze

In many ways, medical writing is its own worst enemy. The reason is that the better the writing, the more invisible it becomes. In contrast to literary writing, where the writing itself is in the foreground and to be enjoyed for its own sake, the aim of medical writing is to transmit complex information and key messages to the reader as unobtrusively as possible. This may be appreciated by some readers, but because most people cannot write well, the invisibility of good technical writing is precisely that—mostly just not seen. For instance, a well-designed table usually looks "obvious", even simple, and may seem as if it took but a few minutes to draft. What the average reader will not perceive are the days of struggle, of grappling with the key message and secondary messages of the table, and experimenting with different designs to produce the best result. The same of course applies to figures, to text, and indeed to overall structure of complex documentation. The quality of the writing will only be obvious to most readers when it is bad—when readers have to rack their brains over some text, a table, or a labyrinth of interrelated documents all of which impede comprehension. Admittedly, many non-writing colleagues do agree that we writers perform a useful function, but this is somewhere between a "glorified secretary" and (at my company) a "walking German-English dictionary". I mention this, not to downplay the essential roles of secretaries and translators, but to stress the unique skill set of writers.

The notion that new technologies will somehow make medical writers redundant arises out of this misconception. It is a notion that has, in different manifestations, been proposed to me over many years. "As far as I am concerned, good science, even if badly written, is all that we need". "A submission is really only about P-values". "With suitable software, a study report can be generated entirely automatically from the data". These are real-life statements that I have noted from senior managers in our company—as it happens, a clinician, a statistician, and a clinical pharmacologist.

Writing Text

I suspect that all professional medical writers have their private collection of awful, or unintentionally hilarious, or plain indecipherable text that they were given to review or edit. Obviously, writers must bring all their language skills to bear on such monsters, and medical prose is of course especially prone to convoluted language. Working on a multi-disciplinary team, the writer usually has to convince the clinician that it is no slur on his or her professionalism for the text to be written simply and clearly for a non-specialist readership.

Writing submission documents, particularly clinical study protocols and reports, can be greatly facilitated by standardization of text modules. Thanks to ICH and other international changes, the scope of such standardization has been much extended. This applies particularly to text that embodies company policy or international GCP requirements, where seemingly innocuous changes to wording can undermine company

standard operating procedures and international regulations. However, clinical trials come in all shapes and sizes, and so standard modules must be devised in different versions to suit different scenarios. These modules can be built into "libraries", and programs such as Word can be embellished with simple macros and on-screen dialogue boxes to facilitate selection of the appropriate text module. Despite such tools, many clinical trials will not fit into the straitjacket of a pre-defined standard, and the writer must review and adapt the standards as appropriate, either for an individual report, a series of reports or a given development. Standard text modules notwithstanding, most of the really important text in a clinical study report will only be written *de novo* as the results of the trial become available and are interpreted, once again drawing on writing skills.

Designing Tables and Figures

"Medical writing" often conjures up "narrative text", but a great deal of medical writers' time is spent on designing tables. Anyone who has worked with tables will know of the many potential pitfalls. Which information is best placed in the table title? How are the columns and rows to be arranged? Which information in the column and row titles? Or footnotes? Which data must be selected, and how should the table be linked to other tables or appended listings? On multi-disciplinary teams, it is often the bio-statistician who needs convincing by the writer that it is not necessary to mention in the table everything that is in the database, that the table is more than an amorphous "container" for any item of data coming off the line printer.

Again, standardization by means of templates coupled with standard statistical programming will facilitate table generation, an activity that is often rate-limiting during the final stages of dossier production. As with standard text, table shells will need frequent adaptation to specific projects, and sometimes, as results become available, alternative designs may emerge as being more appropriate to demonstrate the "message" from the data. The skills and experience of the writer on the team will be crucial to these steps. The application of writing skills to the production of figures is entirely analogous to the generation of tables. With suitable software, libraries of "figure shells", in which wording and figure design are pre-specified, can be created and "populated" with data sets using pre-defined programming.

Building Submission Dossiers

When building submission dossiers, medical writers and their colleagues on project teams are challenged to produce, usually in a timeframe that is frighteningly short in comparison with the overall development time, coherent documentation of hundreds of thousands of pages that will allow regulators access to the mass of data while keeping a comprehensive perspective and a focus on the essential message. This activity has two elements: writing layer upon layer of summary-level documents and assembling the entire package in a logical way, complete with "navigation aids", in other words a clear hierarchical structure, cross-references, indexes and hyperlinks.

Once again, there is a vital need for medical writing skills and experience, and an ability to envisage the entire, finished package very early in its development. This vision will guide the focus on certain studies and analyses, in turn influencing the design of tables and need for certain document modules. Only with this vision can development of the documentation begin far in advance of database closure, and only

this approach will allow a real reduction in overall development time. There is a well-known Chinese saying about the journey of a thousand miles beginning with a single you are in big trouble, at least as far as deadlines are concerned! It is often the insight and experience provided by the writer that prevents those first steps from heading down the wrong road. Pharmaceutical developments frequently do not conform to a standard model, and in addition, much of the guidance is vague or incomplete, or, if applied to the letter, will not result in a reviewer-friendly dossier. Many decisions must be taken as to how to apply regulatory guidance to the dossier in hand. The medical writer will sometimes need to convince the regulatory expert on the project team (who often seem overly in awe of "the guidelines") that a certain amount of creative adjustment is needed to accommodate the information available in a coherent manner.

None of these medical writing activities, which relate to dossier *concepts*, will be greatly affected by new technologies, though dossier publishing tools will tremendously benefit the work of the medical writer in technical dossier assembly. For instance, if cross-referencing can be automatically carried over and updated from individual document level to dossier level pagination series, a second round of validation of these links (which some tools may also convert to hyperlinks in electronic dossiers) becomes unnecessary. The new technologies help sharpen the distinction between the more intellectual and more technical elements of creating documents and dossiers. Medical writers in some environments may be involved in both aspects, but the increasing complexity of the technology may lead to sub-specialization.

Customising dossiers for different pharmaceutical regions (notably the USA, the EU and Japan) consumes medical writing resources during the most critical phase of dossier preparation, with the additional challenge of ensuring cross-dossier consistency. New document management technologies may, to a limited extent, permit simultaneous construction of regional submissions by mapping common elements to predefined locations in different dossiers. However, many submission-level documents are not common across dossiers. The biggest step forward will be a successful outcome of the ICH M4 topic, the "Common Technical Document". If such a step is achieved, it will be medical writers once again who will be challenged with interpreting and applying the guidance to real-life situations. We must not forget that even within Europe, where a "common technical document" has been in force for many years, the various national regulatory authorities only converged slowly; even today, companies experience startlingly different assessments of their marketing authorisation applications by the different European regulatory authorities.

Developing Standards

Standards are in continuous development and always require interpretation. Experience is proverbially the best teacher, and this is nowhere more important than for developing standards, whether for internal company guidance and templates, or for international regulations. Experienced medical writers can and should take the lead or make major contributions when it comes to developing standards for technical documents. During their daily work, writers must apply internal and external guidelines to real-life documents. On project teams, they must integrate cross-functional contributions. Consequently, they are sensitive to the limits of standardization, they gain experience as major users of standards and templates, and hence can refine standards based on practical experience. As I have stressed earlier, standardization must not be a straitjacket. However, the process of deviating from standards must itself be defined

and regulated, and once again, experienced medical writers provide crucial insights towards achieving this.

The new technologies, if they are to be used effectively, will require their own levels of standardization. An important maxim is "requirements drive technology and not vice versa", and medical writers can make vital contributions towards defining requirements that make the application of the new technologies a success.

Looking into the Future

Far from compromising the role of the medical writer, information technology has opened the door wide to an explosion of healthcare information and an awareness of the need for professional medical writers. I was particularly pleased to hear a comment last year from a prominent and ubiquitous European regulator, who told me that in his opinion, medical writing will be a major growth industry in the years ahead. Regulators are, of course, directly on the receiving end of dossier writing, and so perhaps it is not surprising that recognition of the role of medical and technical writing in assuring quality of regulatory documentation should come from that quarter. I hope that senior managers in the pharmaceutical industry will also come to realize that poor writing will mean longer review times and more objections (even if only because of misunderstandings), and may cast a shadow on the validity of the entire data package. All of this leads to delays in review and approval of submissions—delays which are generally entirely avoidable by good writing, which is a small investment relative to the overall costs of drug development, but one that will pay off handsomely when it comes to getting new drugs to the market more quickly.

It is a truism that any tool is only as useful as the craftsman that uses it. With regard to medical writing, we must keep in mind that electronic publishing systems and other software, standard operating procedures and even regulatory guidance, are tools and as such, essentially a means to an end. That end is the flow of healthcare information, whether to regulatory agencies, physicians or the general public. Medical and technical writers are crucially important to the correct application of these tools and optimising the flow of healthcare information.

To quote Bob Bonk, from his excellent recent book *Medical Writing in Drug Development* (New York: The Haworth Press, 1998), medical writers "capture, meld, disentangle, juxtapose, and reassemble biomedical information into logical packages for varied audiences." These activities require not an electronic but a human brain. Medical and technical writers in the pharmaceutical industry must understand the pharmaceutical research and development process, must understand biomedical information, must understand regulatory guidance and its limitations. They must also bring to bear on this knowledge the insight and rhetorical skills needed to understand the audience, hold the reader's attention, present the key message, guide the reader's interpretation, and gain the reader's confidence. They have a bright and challenging future.

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Stephen de Looze presented this paper during the DIA Workshop "Medical/Technical Writing and Associated Technologies" in Paris, Sep 98, under the chairmanship of Dr. Betty Kuhnert, Wyeth-Ayerst Research, USA and Susanne Wedderkopp, Novo Nordisk, Denmark

The Changing Face of EMWA

Results from the questionnaires – Edinburgh, 1997 and Madrid, 1998

by Gerold Wilson and Barry Drees

At the meeting in Edinburgh in 1997, the Executive Committee decided to revive the EMWA traditon of assessing our members' views using a questionnaire to help us make decisions about costs, future projects and, most importantly, which workshops to offer the next year. This worked quite well and so it was done the following year as well. Now that we finally have a second set of data points, we can get a rough idea of how stable the backgrounds and wishes of the membership really are. The questionnaire data also serve to give us a look at ourselves, i.e., what kinds of medical writers are we?

Unfortunately, although the response in 1997, while hardly overwhelming, was fairly reasonable (~50%), the response last year was very disappointing (30%) and thus it is very difficult to draw any conclusions (Tom Lang will never let Barry teach the statistics course if he sees us comparing these percentages). Still, assuming that these questionnaires are representative (which we have no way of knowing), one gets the general impression that things are in equilibrium, at least in terms of those members who attend the meetings and turn in the questionnaires.

An organization needs a good mix between old "regulars" and new members to stay healthy. There are some encouraging signs that we are a dynamic organization that's still growing. We had about the same number of new members at both meetings, although there was a slightly higher percentage of members attending their first meeting this year in Madrid. The fact that the average duration of membership of conference attendees increased by one year this year (if it means anything other than sampling bias) shows that members who attend conferences are likely to remain members. We're also very happy to report that the number of conference attendees who consider the EMWA costs (membership, conference and workshops) to be satisfactory went up in all three categories and was close to 80% or higher in 1998. Awareness of the website has apparently increased, but the number of members with no access to the internet remains stubbornly the same.

Finally, if you find this information interesting or would like to have your information added, please fill out the questionnaire accompanying this newsletter and return it to the editor (fax, post or e-mail) so that the EMWA leadership can stay informed about its membership and what they want.

Summary of the responses for each year (where meaningful)

Category	1997	1998
Response		
Total number	41	29
Rate (approx.)	50%	30%
Satisfied with EMWA costs		
(answered "just right" or "what a bargain")		
Membership	84%	93%
Conferences	57%	79%
Workshops	87%	93%
Prior background		
Research	50%	32%
Pharma. industry	28%	48%
University	13%	16%
Publishing	13%	3%
Biometrics	3%	0%
First heard of EMWA		
Colleagues	54%	63%
AMWA	17%	10%
Literature	10%	17%
Other	9%	3%

Category	1997	1998
Membership		
Duration	2.9 yr	3.8 yr
New member	29%	28%
EMWA provides		
(multiplte answers possible, % of all responses)		
Education	26%	31%
Networking	26%	26%
Information	25%	25%
Social contacts	16%	15%
Freelance work	7%	1%
Other	0%	1%
Previous meeting attendance		
Average (no.)	2.2	2.3
First meeting	23%	33%
EMWA website		
Visited	61%	69%
No access	15%	17%
Unaware	22%	10%
Job status		
Industry	84%	73%
Freelance	16%	17%
Consulting	0	7%
Academic	0	3%

Ten most desired workshops (in order of most popular)

1997	1998
Writing an Investigator's Brochure	Writing an Investigator's Brochure
Advanced Tables and Graphs	Preparing a Dossier
Regulatory Aspects of Drug Development	Regulatory Aspects of Drug Development
Project Management	Writing/Editing for Non-Native Speakers
Statistics	Improving Comprehension
Writing a Clinical Study Report	Advanced Tables and Graphs
Making Effective Presentations	Writing a Clinical Study Report
Data vs. Information: the CER	Introduction to Pharmacokinetics
Punctuation for Clarity and Style	Ins-and-outs of ICH
Freelance Career (Buisness Aspects)	Organising the Biomedical Paper

From the Literature ... Whizz Bang into the Electronic Age

by Liz Wager

Journal editors are (some would say, at last,) thinking seriously about electronic communications and, as websites proliferate, there has been a flurry of articles and even whole issues devoted to the topic. *The Lancet* provided a useful introduction for the cyber-novice with its 'Guide to the Internet' which appeared as a supplement to volume 351 (1998). It includes a short paper on the electronic future of scientific articles, a longer discussion of peer review on the internet, and tips about useful medical websites. The *BMJ* has gone a step beyond discussing electronic peer review and tried to use this method for a paper on its website (www.bmj.com). The responses make entertaining reading but this is a rather tentative experiment, since the paper in question does not present findings from a clinical trial, but is, itself, about the electronic future of journals. So, this electronic trial, while fun and full of polemic, does not answer the question of whether electronic peer review of regular papers will be feasible. However, it does illustrate the difficulties of commenting impartially about the quality of a piece of work (which is what one hopes reviewers will do) since most of the responses dive right in with their opinions about the views expressed in the paper rather than the quality of the work. Rapid electronic response seems to disinhibit the writer – maybe it still feels more like play than work – and it will be interesting to see if this aspect jeopardises serious electronic review of primary research papers.

The BMJ article has the advantage over JAMA that you can pretend to be reading it while gawping over the tastefully erotic pictures which accompany another series on sexual health.

Moving off the subject of electronic communication for a while, the *BMJ* has also looked at the question of whether the identity of reviewers should be revealed to authors. The issue of 02 January 1999 (vol 318, no 7175) contains a randomised trial comparing open versus anonymous review (p.23-27) and an editorial on the subject (p.4). The trial found no difference in the quality of the reviews and the *BMJ* has therefore decided to adopt a policy of open review and will probably list the reviewers at the end of articles ... should be interesting!

Back to the world of cyberspace, *JAMA* devoted a whole issue to computers in medicine (21 October 1998, vol 280, no 15). This contains articles on e-mail consultations, computerised drug alert systems, computer-based decision support systems, and building your own website. Although this issue contains lots of useful reference material it can be a bit heavy going – I made the mistake of taking it on a longish flight and was thoroughly bored by computer jargon at the end of it, but I'd have probably appreciated the individual entries if I hadn't tried to read it from cover-to-cover.

Back on this side of the pond, the *BMJ* produced an equally technical mini-series on quality management of medical information on the internet (28 November 1998, vol 317, no 7171, p1496-1502). However, this has the advantage over *JAMA* that you can pretend to be reading it while gawping over the tastefully erotic pictures which accompany another series on sexual health. I tried to read this one on a train journey and gave myself a crick in the neck trying to ensure that my fellow passengers couldn't read it over my shoulder!

Until computers become as convenient as paper journals for reading on the hoof, I think paper will remain a handy format and reports of the death of paper journals are premature. However, the net is opening up some interesting possibilities which will affect all of us involved with medical communication so keep watching the screen and happy surfing!

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CORRECTION♦CORRECTION♦CORRECTION

E-mail address is corrected from last issue!!!!!!

!!! FREELANCE OPPORTUNITY !!!

San Francisco-based technical translation company is looking to commission European medical writers to write stories for a monthly medical device newsletter entitled "Medical Device Translation News."

Target audience: U.S. medical device/pharmaceutical regulatory affairs personnel who wish to stay current with regulatory changes and language issues/requirements within the EU.

Competitive compensation paid upon delivery of article.

Please send resume and writing sample to: monique@luz.com
or
Monique Rivas, 541 8th St., San Francisco, CA 94103, USA
Tel: (+1) 415 241 0520 Fax (+1) 415 241 0504

Meetings of Interest

by Sarah Heritage

The following are listed as a service to EMWA members. 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

Date	Meeting/Sponsor	Location
Mar 12 **EMWA**	**Medical Writing (German language)** FORUM Institüt for Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 502	Zürich, Switzerland
Mar 15 - 16	**Pharmacokinetics as Related to Drug Discovery and Development** Management Forum Ltd., 48 Woodbridge Rd, Guildford, Surrey, GU1 4RJ, UK Tel: (+44) 1483 570 099	London, UK
Mar 23 - 25	**Introduction to Clinical Research** 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
Mar 25	**Introduction to Pharmacokinetics and Medical Statistics** 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
Mar 30-31 **EMWA**	**Rapports Medicaux, Medical Writing* (French language, translations available)** Institute for International Research Tel:(+33) 1 46 99 50 10 or (+33) 1 46 99 50 00; gres@iir-fr.com	Paris, France
Apr 21-22	**Statistics and Regulatory Guidelines** Drug Information Association Postfach-4012 Basel, Switzerland Tel: (+41) 61 386 9393; Fax: (+41) 61 386 9390; diaeurope@stepnet.de	Prague, Czech Rep.
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-861929 München, Germany Tel: (+49) 89 993 9130; Fax: (+49) 89 993913 160; info.muc@kendle.com	Munich, Germany

*** Affiliation with EMWA!! EMWA members get 15% discount on conference fee!**

Coming Next Issue . . . (Spring)

Preconference issue

Welcome to Copenhagen!

There's a lot more to an EMWA conference than workshops and socials. Find out about the city with "wonderful" in its official title. We'll also be giving full details of the conference – it's not too late to make your plans!!

☞ NEW SERIES!!

The Lighter Side – The Strange World of Adverse Events

Julia Cooper

Hey, who says *The Write Stuff* hasn't got a sense of humour? Yes, back by popular demand, the famous (or infamous) EMWA Journal humour column is finally resurrected! 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.

The Freelance Contract

Cathryn D Evans

An experienced freelancer offers a sample contract representative of those she uses. The sample given is specific to projects negotiated on an hourly consultation basis for pharmaceutical, biotechnology, or other companies. [reprinted from the AMWA Journal with permission].

☞ NEW SERIES!!

Key Pharmaceutical Documents I: The Patient Information Sheet

Judi Proctor

Here we kick off our new series where we'll be hearing about the various key regulatory documents written by medical writers in Europe (Study Reports, Protocols, Investigator's Brochures, Expert Reports, Written Summaries, and lots more). We start off with the Patient Information Sheet. Most of us are scientists or former scientists writing for others of the same ilk. What's it like to write for a completely different kind of reader?

☞ NEW SERIES!!

Medical Writing as a Non-native Speaker

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 here. In this series, edited by a long-time EMWA member and non-native speaker, we will explore the special challenges and opportunities in medical writing as a non-native speaker.

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