
The Newsletter from the European Medical Writers Association
Chapter of the American Writers Association

Winter, 1993

So you're in Basel, now what? or What to do in Basel besides attending the EMWA meeting

Aaron Bernstein

The announcement flyers are out, the program finalized and arrangements made at the Basel World Trade Centre. Now it's your turn ... to register. In case word hasn't reached you, the upcoming Annual EMWA meeting will take place in Basel, Switzerland, on 24-25th February, 1994. A glance at this year's program boasts two worthwhile workshops and a promising line-up of speakers. More importantly, it's our once-a-year chance to meet old friends and network with new ones. But there's more to this meeting's venue than the offerings described in the program.

Following closely on the heels of the Basel Carnival 'Fasnacht', this year's EMWA Annual Meeting promises to be especially exciting. Fasnacht is a three day event in which 10,000 of Basel's 200,000 inhabitants don extravagant costumes, play fifes and drums and devote themselves to a cult which is believed to pre-date christianity! As the invitation form indicates, it is recommended that you come to Basel the day before the official meeting starts so that you can enjoy the last day of the carnival. But be warned, the atmosphere is infectious and you never know when you'll meet one of the many roving bands of musical merry-makers.

After the meeting, consider spending the weekend in Basel. Its location at the point where Switzerland, Germany and France meet, makes it the ideal location for day trips.

In Basel itself there is the Fine Arts Museum (Kunstmuseum) containing 15th and 16th century Swiss and German masterpieces plus an impressive collection of modern art from Impressionism to the present day.

Alternatively try the Zoological Garden, founded in 1874 and home to 5,600 species. The zoo specializes in rearing threatened species such as rhinos, gorillas and bears.

The Alsace, France contains three noteworthy towns within 90 minutes from Basel: Strasbourg, Colmar and Mulhouse. An enjoyable day can be spent touring the famous motor routes in the region which pass through quaint medieval towns, vineyards, tobacco fields and hundreds of fortified castles.

The German border with Switzerland contains a 106 mile stretch of the famous Black Forest offering the outdoor attractions of woods and streams along with the curative powers of the springs.

For more information contact the Basel Tourist Office (+41-61-261-50-50 / Fax +41-61-261-59-44).

Notes from the editor

Welcome to the second issue of the EMWA 'Journal Europe'. The observant amongst you will notice a change of typeface -- due to the fact that, as Connie Grogan was changing jobs, I agreed to prepare the newsletter. This was an enjoyable experience for me, but readers will have to make do with the limitations of my skills and computer, which aren't up to proper desk top publishing.

This issue focuses on training. We approached several companies offering training courses which might be of interest to medical writers. The result is that several are offering discounted or even free places to EMWA members, and several companies have sponsored this newsletter. We are very grateful for this cooperation and encourage members to take a look at the courses on offer.

The newsletter also includes reports of a number of conferences and meetings. You may notice some familiar names among the authors -- Aaron Bernstein, EMWA President reports from the Annual AMWA meeting, and there are reports from me on meetings on pressure on communicating results and the peer review process. If you object to this newsletter domination by the President and Acting editor, there is a very simple solution -- write something yourselves! As an organization of medical writers we should not be shy of putting pen to paper! Connie and I look forward to receiving your contributions for the next newsletter which we plan to put together in Spring 1994. In the meantime, I hope you enjoy the newsletter and look forward to seeing you in Basel.

Liz Healing, Acting Editor

Contents

So you're in Basel, now what? <i>Aaron Bernstein</i>	1
Editor's page <i>Liz Healing</i>	2
Impressions from the AMWA Annual Conference 93 <i>Aaron Bernstein</i>	3
Pressure on communication of results in clinical research <i>Liz Healing</i>	4
Therapeutic related courses for medical writers <i>Jacky Sayers</i>	5
Effective writing for biomedical professionals <i>Liz Healing</i>	6
International congress on peer review in biomedical publication <i>Liz Healing</i>	7
DIA Eurometing: Managing the interface between benefit and risk <i>Thomas Brown</i>	8
Future courses	9
EMWA Officers	12

Impressions from the AMWA Annual Conference 1993

Aaron Bernstein

The most significant observation I made at this year's AMWA Annual Conference in Atlanta, Georgia, was the enthusiasm for the establishment of the EMWA Chapter as evidenced by outgoing AMWA President, Dr Betty Cohen's, reference and welcome to our Chapter in each of her speeches.

Having attended the Toronto AMWA Annual Conference in 1991, I was already aware of the value of the AMWA Workshops. This year, as the EMWA Chapter delegate to the Board of Directors, I was also able to learn a few interesting facts about some of AMWA's 'behind the scenes' activities -- here are some of them.

- A record 650 of AMWA's approximately 4,000 members attended 77 workshops of the annual conference.

- The *AMWA Book of Biomedical Communications: Selected Training Topics*, a new AMWA publication written by Workshop leaders of Core Curriculum Courses based on their handouts and course materials will be available soon. The 24 chapters cover: writing skills, editing skills, presentation skills, business skills and biomedical documents. This book is of special interest to European members, since it is specially designed for people who cannot attend AMWA workshops.

- AMWA recently endorsed a training programme sponsored by the Pharmaceutical Advertising Council (PAC) Educational Foundation. This indexed and annotated reference manual and self-study workbook will cover FDA regulations, CME (continuing medical education)

guidelines, AMA guidelines on professional ethics, anti-kickback legislation and PMA (Pharmaceutical Manufacturers Association) practice codes affecting our professional interactions.

- A Japanese Chapter? Many Japanese nationals have attended the AMWA annual conference and are interested in eventually forming a Japanese chapter.

- AMWA is undertaking a salary survey of members. This will provide information such as distribution of salary ranges by category and region of employment.

- AMWA membership outside North America has grown by 42% since 1991. Overall AMWA membership grew by 12% during this period. All but one of the 19 chapters expanded.

- An AMWA Task Force on Scientific Writing has been established to address a 1991 FDA 'concept paper' on CME Provider/Industry collaboration which proposes, in part, to restrict both in-house and freelance medical writers within the pharmaceutical industry. This Task Force presented to the FDA an overview of the roles of medical writers in the preparation of CME materials and other industry documents, including FDA submissions. The association's involvement on this issue has increased awareness of AMWA within the scientific and pharmaceutical community as well as in the FDA.

As you can see, AMWA does more than provide educational workshops. If next year's conference in Phoenix, Arizona is anything like this year's meeting it will be characterized by comradeship and lively discussions, both during and between workshops and plenary sessions.

Pressure on communication of results in clinical research: potential for improper practice

Meeting held at the Royal Society of Medicine, London, 13th October 1993

Liz Healing

Despite the cumbersome title this was a lively meeting, bringing together the views of journal editors, stock market analysts, the investigators who actually perform the trials, and the companies which sponsor them.

Most journal editors guard the originality of papers fiercely and are not happy to publish findings which have been published anywhere else. Most investigators accept this stipulation and, although sometimes frustrated by the length of time it takes journals to actually print their findings, accept this as a condition of publication in respected, peer-reviewed journals.

Conflict may arise, however, when the results of scientific research could influence a company's fortunes to the extent of affecting its share price. In the UK, all publicly listed companies have a duty to divulge such price-sensitive information, usually through a formal stock exchange announcement or press release, to reduce the risk of 'insider dealing' or creating a false market.

The problem is in determining what information really is so crucial as to be price sensitive, and how to keep both the stock market and journal editors happy. While most clinical trials are unlikely to affect company share price, since they are simply a small part of a total picture, some can have major effects. The meeting heard

from speakers involved with the controversial Concord trials of the efficacy of AZT (zidovudine) in HIV-positive patients, which had major implications for Wellcome.

Investigators talked about the importance of discussing the results with all participating centres and doctors, and also making results available to the patients who took part.

Another example of price-sensitive results are those from huge studies or meta-analyses such as the big cardiovascular studies ISIS and GISSI which have involved tens of thousands of patients worldwide. The organizers were careful to arrange for public announcements to coincide with publication and, because of the importance of the study, could also arrange rapid publication of the results and circumvent journal lead times.

Clearly, most trials can be published in the normal way, and subject to the normal delays, without fears of upsetting the stock market or opening the way for insider dealing. However, for very crucial trials, the current journal guidelines preventing prior publication may cause serious problems for the sponsoring company. Writers need to be aware of the sensitivity of such information and the importance of developing a suitable strategy for presenting important findings to the press without jeopardising publication in the scientific literature.

Therapeutic related courses for medical writers

Jacky Sayers, Healthcare Education Services Ltd

The pharmaceutical industry is no different from any other in that it possesses its own technical language and jargon which can be totally unintelligible to outsiders. Add to that the terminology related to specific disease areas and it is clear that there are many opportunities for misunderstanding and poor communication. Medical writers have an important role to play in demystifying the drug development process by preparing clear, concise and understandable documents.

Quality assurance

It could be argued that, given a suitable educational level, a writer should be able to prepare clinical trial reports, sales and marketing material and journal articles from basic data, without having an in-depth knowledge of the specific therapeutic area in question. If the writer does have such knowledge, however, he or she will be able to appreciate the relevance of the document being prepared, rather than just assembling the information, and undoubtedly find the task more stimulating and rewarding.

Understanding the typical patient profile and the processes of presentation, diagnosis and clinical intervention depend on a clear understanding of the clinical management issues.

Confidence in his or her therapeutic area knowledge should help the medical writer become a more valued member of the drug development or strategic marketing team.

Manuscript preparation and submission

With an understanding of a specific therapeutic area, the significance of clinical

trial results becomes clearer and consequently report writing is more productive. The writer can take on a more analytical role highlighting relevant issues and reaching conclusions based on reported findings. The preparation of marketing material, symposia manuscripts and journal articles becomes more directed if the writer is aware of the patient's needs, the disease management process and the type of physician likely to be treating these individuals. It will undoubtedly help in the process of choosing the most appropriate journals for eventual publication. Therapeutic area knowledge allows the writer to prepare material that is relevant to the proposed reading audience and user friendly for the people working with the information presented.

Training opportunities

Networking within your own company to ensure that you are included as a potential delegate on any in-house therapeutic related training would be a cost-effective introduction to disease related education. Healthcare Education Services Ltd, on behalf of EMWA, will be undertaking an impact evaluation exercise to explore the relevance of disease related training to medical writers within the pharmaceutical industry. A selected representation from EMWA will be offered complimentary places on HES courses over the next year. Delegates undertaking this training will be asked to assess its relevance and impact on their day to day work.

If you are interested in participating in this survey, please contact:

Dr Jacky Sayers,
Healthcare Education Services Ltd,
31 Albany Street, Edinburgh,
EH1 3QN Phone 031-557-2477, Fax 031-
557-6778

Effective writing for biomedical professionals

Oxford Professional Development Courses

This course is designed for anyone working in the healthcare or biomedical field who needs to present written information, whether in the form of technical reports, scientific papers, newsletters or even memos. When I attended, the other delegates were all relatively experienced, either scientists involved in basic or clinical research or writers, and all working within the pharmaceutical industry. The course therefore concentrated on scientific papers, but many of the topics and tips could be applied to anything written.

Dr Jane Fraser, the course's enthusiastic presenter, is a freelance medical writer and consultant who previously worked at Adis and the Medicine Group. In addition to the Oxford courses, the University also provides in-house training tailored to individual companies' needs.

The first day covered some of the basic rules of good writing, with the particular message of 'know your audience'. Principles were explained with apt, and often entertaining, examples. The class particularly relished wielding their newly acquired skills to attack examples of poor writing. The day consisted of presentations, backed up by extensive course notes, interspersed with informal discussion and practical exercises, some done in groups, some as individuals. The small group size (each course has a maximum of a dozen delegates) ensured plenty of attention from Dr Fraser and individual help with exercises. This is probably particularly important in groups with a greater range of experience, abilities and native tongues. We were a relatively

homogeneous group, native English speakers with a fair bit of experience in writing clinical trial reports and publications.

Each part of the scientific paper (Introduction, Methods, Results, Conclusion) was covered in detail. There was also an exercise in abstract writing.

The second day worked on refining the principles outlined on Day 1, aiming to make writing not only technically correct but also enjoyable to read. The class also considered journalistic tricks which may be useful for getting the reader's attention. The final section was on writing for presentations, including practical tips on preparing slides and using illustrations such as graphs and figures.

Judging from evaluations by earlier delegates, the great majority enjoyed the course and found it useful -- although it obviously can be difficult to cater for widely differing expectations and abilities. Oxford University's Continuing Education Department, Rewley House, provides a pleasant setting but is relatively inaccessible by car, as parking in Oxford can be a problem. However, it can be reached easily by train or coach with regular services from London and Heathrow. Residential accommodation is sometimes provided in Rewley House itself, sometimes in nearby hotels, which may increase the cost of attending. Courses in Basle and Copenhagen are held in hotels which probably have more facilities but are also more expensive (£90-£100 per night on top of course fees which cover lunch and coffee only).

Overall, a useful and enjoyable course, and well worth considering especially as the organizers are offering a 10% discount for EMWA members (see leaflets for details of future courses).

International congress on peer review in biomedical publication

Chicago, September 9-11th 1993

Liz Healing

As my productivity is measured solely in terms of the number of articles I manage to get published in peer reviewed journals, the process of peer review has particular interest for me. I was therefore very glad to be able to attend this second congress on peer review in biomedical publication. One of the attractions was the chance to rub shoulders with the great and the good from the world of biomedical journals. Editors from the 'big name' journals, such as the NEJM, Annals of Internal Medicine, JAMA and the BMJ were there, along with many from more specialized publications. Both academic and technical editors were represented, so we heard the views of both those who commission the reviews and act on their advice, and those who actually do the reviewing. We also heard from the paid staff of larger journals and publishing houses and from those within the pharmaceutical industry. In many cases, presenters had experience of both reviewing or editing, and having their own work edited or reviewed.

The meeting consisted of short presentations of original research or observation on the peer review process. Some gave the impression of confirming the obvious, but this is a new field of research so one should not judge too harshly and it may be useful to quantify what we already know. Others were elegantly designed studies showing the power or pitfalls of peer review.

Several papers showed that peer review served not only to filter papers, and form the basis of accepting or rejecting them for

publication, but also substantially improved their quality. Statistical review may be particularly crucial, and is being increasingly used.

We learned that the most useful reviews, in the eyes of journal editors, come from young (<40) academics from major institutions, well known to the editor and, where possible, unaware of the identity of the paper's author. The older and more eminent are less reliable reviewers. One survey also found that women provided reviews more quickly than men!

There was much discussion as to whether it really is possible, and desirable, to hide the identity of the paper's author from the reviewer. This was generally found to reduce bias, but especially in small specialized fields it can be almost impossible to completely blind the reviewer. Conversely, some speakers favoured open review where the identity of the reviewer was revealed, and encouraged direct dialogue between author and reviewer.

Several examples of failure of the peer review process were presented. Problems included excessively slow reviewers, harsh and bigotted criticism and, in a few cases, plagiarism of research ideas or results. Authors also came under the spotlight and examples of plagiarism and multiple publication were exposed.

Publications arising from industry-sponsored symposia, and published in sponsored supplements, were critically assessed and found to fall short of the high standards set by the parent journals. This suggests that the peer review process is not so stringently applied in sponsored supplements.

Abstracts presented at national meetings were also shown to be lacking, and only

about half of them went on to be published in full. Although abstracts are reviewed for selection, it was suggested that they should not be regarded as fully peer reviewed since they don't include enough information for a full assessment.

Lively discussion followed many of the 10-minute presentations and the experience of the audience added many thought-provoking anecdotes to either support or refute the findings presented. The variety of methods used by different journals provided opportunities to share very different experiences.

The overall conclusion of the meeting was that, despite its problems, peer-review, like democracy, was easy to criticise but hard to replace -- one editor summed it up as 'crude but indispensable'. Lively dialogue and research should improve the process and remove its worst excesses but it remains the best tool we have for ensuring a high standard of scientific papers in biomedical journals.

DIA Eurometing

10-13 October 1993

Session V: Managing the interface between benefit and risk

Thomas Brown

Benefit/risk assessment is aptly summarized in the question 'is the cure worse than the disease?' The point was made that benefit/risk for a newly developed drug must be compared with the benefit/risk of alternatives, including other treatments or no treatment. This may consider therapeutic efficacy, cost, benefits, patient preference and effects on society.

The most common measures of benefit in drug development are mortality, morbidity, hospitalizations and clinical indicators. However, another measure is the health status as felt by the patient. Outcomes analysis is an attempt to measure health status. Common parameters include health perception, functional status (ie limitations on activities), performance, feeling of well-being and satisfaction with care. Outcomes trials are often retrospective (rather than prospective, randomized trials) and comparisons are against alternative treatments rather than placebo.

Clinical trials can provide benefit data in the form of safety and efficacy data, patient preference and quality of life, and economic data such as drug costs, number of physician visits, time spent in care or treatment and resource utilization. In trying to quantify outcomes such as overall well-being it is difficult to collect the right data in an appropriate way. The point was repeatedly made that some drug companies abuse the idea of outcomes analysis by selecting variables that are obvious extensions of therapeutic efficacy. Although such measures do confirm that

efficacy is good for the patient, this is often not a true outcomes analysis.

In designing outcome measurement, several points need consideration:

- What question needs answering?
- What are the constraints of the trial, eg is the follow-up long enough, are exclusion criteria likely to affect outcome data?
- Which instrument to use?
- Timing of measurements
- Premature withdrawals (treatment failures and AEs are also outcomes)
- Multinational trials may pose cultural and linguistic difficulties.

A survey from the Centre for Medicines Research (UK) showed that 70-80% of EC and US drug companies perform quality of life (QoL) studies as part of their R&D. About 50% of companies use QoL as early as Phase II. QoL data may also be used for price negotiation and as criteria for project termination.

How to prepare a state of the art regulatory risk/benefit summary

Preparation of the summary should begin with a review of the preclinical toxicology and pharmacology data, followed by clinical pharmacology (dynamics and kinetics). Background provided by such a review is useful in interpreting clinical trial data and post-marketing experience. Many benefit/risk summaries are flawed because they do not consider early animal data and primary clinical pharmacodynamic activity of the drug at therapeutic concentrations.

Clinical pharmacodynamic studies are useful in justifying the recommended dosages, and it is important to show whether the dose-response relationship is consistent with the proposed mechanism of drug action. It is generally expected that the most common adverse reactions will

reflect the primary pharmacodynamic activity of the drug. Pharmacodynamics and kinetics are important in separating out AEs that result from the drug's intrinsic activity from those that could not be predicted from drug activity.

Too often, little attention is paid to pharmacokinetics, especially in subpopulations that are relevant to the indication and treatment, and which are discussed in the clinical sections of the application.

In formulating the SPC, it is almost never appropriate to recommend a single dosage. Reviewers expect the company to propose, and justify, a range of doses to fit circumstances.

The benefit/risk summary should quantify risk. Although this is difficult, it is considered a key issue. The summary should also identify specific risk factors. Especially for a drug which does cause serious adverse reactions, risk factors can salvage a drug review. Restrictions on use, based on risk factors, can be incorporated in the SPC and allow approval of an otherwise unapprovable drug.

The benefit/risk summary should define the margin of safety for human use, and assure the reviewer that it is high. The summary should also describe the company's intended post-marketing strategy for following adverse reactions.

Future Courses

The Oxford Professional Development Courses

Effective writing for biomedical professionals

31 Jan-1 Feb 1994, Oxford

21-22 February 94, Copenhagen

Advanced writing for pharmaceutical marketing

9-10 February 1994, Oxford

23-24 February 94, Copenhagen

Course fee £495 plus accommodation*

Effective project proposals

7-8 February 1994, Oxford

Details from:

University of Oxford Dept for Continuing Education

1 Wellington Square

Oxford OX1 2JA

Tel +44 (0)865-270373

Fax +44 (0)865-270284

* 10% discount for EMWA members

What publishers want

Authors in Science consultancy

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Authors in Science Consultancy courses enable scientists and others to write accessibly for a specified market, whether book, journal, newspaper or periodical.

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Dates/frequency: by arrangement to fit individual schedules, including weekends

Cost: £300, including course materials and initial consultation and planning

Open to: medical and behavioural scientists, academics and others who wish to write more and to properly promote their work and/or subjects.

Location: London, with initial postal work-up

Other information: project specific guidance, including assessment, restructuring, rewriting and presentation also provided.

Note: fees include course materials and initial work-up. Costs can be shared with a colleague or associate (who need not be from the same discipline) by negotiation.

Discounts available when a colleague or associate signs up for a separate series.

Details from: Sally Crawford, Authors in Science Consultancy

PO Box 4YP, London W1A 4YP, UK

Tel 071-637-1759, Fax 071-636-5384

Alzheimer Journalism Fellowship

The Sigma-Tau Foundation Alzheimer Journalism Fellowship recognizes contributions in increasing awareness about Alzheimer's disease. Fellowships will be awarded for consumer print media, radio/television and professional science publications. In each category, 1st prize winners will receive a one-week all expenses paid fellowship to the Italian Spoleto Festival of Culture and Science in Umbria in July 1994. 2nd and 3rd prize winners will receive cash awards.

All entries must have been published or broadcast between 16/1/92 and 15/1/94. The deadline for receipt of entries is February 4th, 1994.

For entry forms and more details contact:
The Sigma-Tau Foundation
Awards Chairperson
PO Box 3179, Gaithersburg, MD 20885-3179, USA

or call 1-800-447-0169

Maxwell Courses

For information about the 1994 programme of Maxwell Clinical Research Skills and Maxwell Foundation Courses in Clinical Research contact:

Sally Edwards
Gabbay Group Training
Ambassador House
8 Carlton Crescent
Southampton, SO1 2EY
UK

Tel +44 (0)703-230511

European Association of Science Editors (EASE)

Fifth General Assembly and Conference

Editing, ethics, electronics and economics

Hotel Gellert, Budapest, Hungary

24-28th April, 1994

For further information contact:
Maeve O'Connor, EASE secretariat
49 Rossendale Way, London, NW1 0XB, K
Tel +44 (0)71-388-9668
Fax +44 (0)71-383-3092

Other organizations:

IFSE

International Federation of Science Editors

aims to improve scientific communication throughout the world and provide a focal point for representation of editors through UNESCO, the International Council of Scientific Unions (ICSU), the International Standards Organization (ISO) and other bodies.

Annual membership is US\$40 for individuals, \$100 for organizations

For details contact:
IFSE secretariat
c/o School for Scientific Communication
Mario Negri Sud Research Institute
66030 S. Maria Imbaro
Italy

Tel +39 872 5701
Fax +39 872 578 240

President

Dr Aaron B. Bernstein
F. Hoffmann-La Roche
CH-4002 Basel
Switzerland

Tel +41-61-688-4504

Fax +41-61-688-8018

Vice President

Mrs Leen Ashton-Vanherle
Janssen Research Foundation
B-2340 Beerse
Belgium

Tel +32-1-460-3734

Fax +32-1-460-2841

Treasurer

Dr. Philip H. Cooper
F. Hoffmann-la Roche
CH-4002 Basel
Switzerland

Tel+41-61-688-3703

Fax+41-61-688-8018

Secretary

Dr Remy Brossel
Biologie & Industrie
158, Avenue de Paris
49300 Vincennes
France

Tel +33 (1) 43-98-07-51

Fax +33 (1) 43-74-03-04

Finance

Dr Sheila Burns
Gabbay Group
Ambassador House
8 Carlton Crescent
Southampton, SO1 2EY
UK

Tel +44 (0)703-230511

Fax +44 (0)703-230513

Programme

Dr Kate Beardshall
Boots Pharmaceutical Co Ltd
Pennfoot Street Bldg E50
Nottingham, NG2 3AA
UK

Tel +44 (0)602-498-519

Fax +44 (0)602-498-091

Publicity

Ms Debbie Taylor
Smith Kline Beecham Biologicals sa
Rue de l'Institut 89
B-1330 Rixensart
Belgium

Tel +32 2 656 85 50

Fax +32 2 656 81 32

Freelance directory

Dr Linda Dearden
Clinical Investigation
Boots Pharmaceuticals
Nottingham, NG2 3AA
UK

Tel +44 (0)602-492335

Fax +44 (0)602-498091

Newsletter

Ms Liz Healing
Janssen Pharmaceutical
Grove, Wantage
Oxon, OX12 0DQ
UK

Tel 44 (0)235-777391

Fax 44 (0)235-777501