EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast - July 2019

Save the date! 49th EMWA Conference Malmö, 7th - 9th November 2019

Expert Seminar Series

Do you have any suggestions for topics of interest for the next ESS?
We cannot guarantee we will be able to include them all, but all suggestions will be considered and accommodated if possible.

Please send your suggestions to:
maria.kotlowska-haggstrom@propermedicalwriting.com or
ed@emwa.org

EMWA Webinar Programme

On July 25th at 2:30 PM CET we will have a webinar on **"Nutrition basics"** by Dr. Carolina Rojido.

Here's a brief introduction:

Since medicine and nutrition are closely intertwined, medical writers may be asked to write about nutrition. However, because we all eat, we are all experts about it...in a way, but this doesn't mean we are well versed in science. Additionally, we often receive conflicting information about nutrients, diets, research results, etc. This webinar aims to clarify basic facts that will prove useful professionally and personally.

Please click here to register for this webinar.

On August 29th at 14:30 pm CET we will have a webinar OPEN TO NON-EMWA MEMBERS: **'Oh, Vienna. Impressions of my first EMWA conference'** where several EMWA members will participate in sharing their experiences.

Pharmacovigilance News

- New long-lasting implant Sixmo (buprenorphine) to treat opioid dependence in the EU; an additional study is required in patients in Europe to further evaluate risks associated with implant insertion and removal.
- EMA has started a review of medicines containing fluorouracil, to examine existing screening methods and their value in identifying patients at increased risk of severe side effects (neutropenia, neurotoxicity, severe diarrhoea, and stomatitis).
- EMA has started a review of medicines containing estradiol (used to treat vaginal atrophy through menopause) in order to assess the risk of estradiol being absorbed systemically.
- EMA has started a review of medicines containing fosfomycin (used to treat infections) in order to assess the risk of increasing resistance to antibiotics.
- Use of multiple sclerosis medicine Lemtrada is restricted while EMA review is ongoing
- Restrictions in the use of Xeljanz (tofacitinib) (approved for treating rheumatoid arthritis, psoriatic arthritis, and severe ulcerative colitis) while EMA reviews risk of blood clots in lungs
- Withdrawal of marketing authorisation application for fenspiride cough medicines due to heart rhythm problems.
- EMA has published its 2018 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission. The new EudraVigilance system improves reporting of side effects and detection of safety signals.
- Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on safety signals adopted at PRAC's May 2019 meeting
- PRAC monthly infographics (statistical overview of PRAC activities) available on PRAC webpage from May 2019 onwards
- ICH guideline E8 (R1) on general considerations for clinical studies – Step b released for public consultation (deadline for comments 30-Sep-2019)
- EMA Annual Report 2018 published

To read more, please click here

Regulatory Public Disclosure News

- EMA Clinical Data Disclosure Activities and Guidelines Development: Continuing Hold
- Update on EU Clinical Trial Regulation (CTR): Clinical Trials Information System (CTIS)
- ESTIMAND: EMA SAWP Advice Open for Comment
- CBMRT: Free meetings in the US and EU on transparency
- CORE Reference Team's Peer Review Publication in Press

To read more, please click here

Medical Devices

BSI Webinars
BSI as a Med Dev Notified Body has a number of support webinars which are free and will be useful. Can be consulted here.

- MDR Conformity Assessment Routes – Dr. Jayanth Katta
- ISO 14971:2019 Risk Management for Medical Devices – Dr. Peter Bowness
- Symbols (15223) + plus EN 1041 replacement (ISO 20417) – Dr. Peter Bowness

Conformity assessment brochure is stored here

A new document to help with conformity assessments and the regulatory requirements which are per class of device can be consulted here.

Medical Writing Journal

Upcoming issues of Medical Writing
The following are the next planned issues of Medical Writing. If you're interested in contributing a feature article to a specific issue, please contact the guest editor. For regular section contributions or other enquiries, please email mew@emwa.org.

- **September 2019 –** Trends in medical writing (Guest editor: Somsuvro Basu).
- **December 2019 –** Artificial intelligence & digital health (Guest editors: Evguenia Alechine and Martin Delahunty). Deadline for feature articles: September 9, 2019. Contact: ealechine@epsilonsci.com or martin@inspiringstem.org
- **March 2020 –** The data economy (Guest Editors: Raquel Billiones and Sam Hamilton). Deadline for feature articles: December 10, 2019. Contact: sam@samhamiltonmwservices.co.uk or medical.writing@billiones.biz
- **June 2020 –** Visual communications (Guest Editor: Ana Goios). Deadline for feature articles: March 10, 2020. Contact: anagoios@gmail.com

Our Planet Needs Your Help

EMWA member Evguenia Alechine needs our support for a cause that is relevant to all of us.

As a science communicator, Evguenia has been selected to be part of Homeward Bound, a global leadership program for women in science that is addressing climate change to save our planet.

To be able to participate in this initiative, she has to raise US$ 18,000 and needs all of us to make that possible. Go to her crowdfunding page to learn more about the project and support her by making a donation and sharing this important cause with your network.

Professional Indemnity Insurance - 20% Discount for EMWA Members

Did you know that EMWA members get a 20% discount on their Professional Indemnity Insurance?

Established in 1992, PIA Commercial works closely with their clients to provide a tailored range of specialist insurance products for both individuals and businesses. Please contact PIA Commercial at info@PIACommercial.com for any queries or to receive a personalised quote. Or go to their brand-new updated website at www.piacommercial.com to view their extensive range of personalised insurance plans for businesses and individuals in the life science, biotechnology, and healthcare industries

Keep up to date with their business news and industry insights by following them on LinkedIn, by searching 'PIA Commercial'.

Leading medical journals to restrict access to pharma industry research

Analysis of open access policies of leading medical journals, published in BMJ Open

Leading medical journals restrict access to industry-funded research, shows a study conducted by researchers at Oxford PharmaGenesis, published in BMJ Open today. This is likely to impede further research and delay patient benefit.

The study shows that, although 60% of high-impact medical journals provide immediate open access under the gold standard Creative Commons Attribution (CC BY) licence, 95% of these offered this option only to authors funded by non-commercial organizations. Just one journal included in the analysis (The BMJ) offered a CC BY licence to any funder who requires it, even pharma companies.

"Our research shows, for the first time, that the availability of open access options depends on the funding source", comments Tim Ellison, Senior Medical Writer at Oxford PharmaGenesis and lead author of the article. He goes on to say, "Open access publishing is important because it ensures that anyone anywhere in the world has free access to high-quality, peer-reviewed evidence. Academic research funders, such as the Wellcome Trust and the Bill & Melinda Gates Foundation, and open access initiatives like Plan S, are increasingly requiring that research is published open access under a licence that allows the broadest possible use. By not offering authors reporting commercially funded research this option, most leading medical journals' policies are not aligned with open access guidelines."

Tim Koder, Communications Director at Oxford PharmaGenesis and co-author, says,

"Journals currently restrict access to medical research funded by the pharma industry – that's half of medical research, including most of the evidence supporting new medicines. If pharma joined non-commercial funders in requiring open access under a gold standard CC BY licence, then leading journals would need to change their policies or stop publishing industry-funded research."

Chris Winchester, CEO of Oxford PharmaGenesis and another co-author of the article, adds, "At Oxford PharmaGenesis, we are proud to be advancing medical publishing by the pharma industry as part of Open Pharma and by conducting our own research. This led us to update our publication policy to commit to publishing our own research open access under a CC BY licence. We are delighted that The BMJ has honoured that commitment and hope this will encourage others to follow our lead."

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