

EMWA Newsblast - May 2020



EMWA 2020 AM Meeting

Don't forget to attend our **Annual Meeting at 17:00 CEST (16:00 BST) on Wednesday 06 May 2020**. Here is the [GoToWebinar link](#) to access the virtual AM.

Note: please register as an attendee using the GoToWebinar link above **prior to the AM**.

We look forward to having as many of you there as possible!

The EMWA Expert Seminar Series (ESS) will go virtual!

We are pleased to announce that several ESS sessions initially planned for Prague will be held virtually. We will kick off with the Medical Device ESS in early June.

We have the following topics lined up.

Speaker 1: Jonathan Sutch of BSI UK will speak on "Drug/ device combination regulation including Article 117."

Speaker 2: Richard Houlihan of Eudamed will speak on "The new EUDAMED under the MDR."

Dates and other details will be provided soon. Stay tuned!

Ambassador's Programme

Alison Rapley presented a workshop and a promotional talk for EMWA at the City University of London on 12 March just a week before the Corona virus lock down. Altogether 20 students attended and the feedback was very positive feedback as it was when Alison gave this talk last year.

On 19 May Gauri Jawdekar-Abraham will give a virtual presentation on medical writing and EMWA for the German Cancer Research Institute as part of their Career Coffee series. This will be the first virtual presentation held by the Ambassador's Programme.

Due to the corona virus lock-down participation of EMWA Ambassador representatives at the MediWeek in Birmingham (17-18 Mar) and by Abe Shevack at the Parexel Academy in Berlin (21 April) were cancelled.

Greek Translation of the Joint Position Statement on Predatory Journals

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) recognize the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices undermining the quality, integrity and reliability of published scientific research. The joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.

By joining with AMWA and ISMPP in both developing and publicizing the Joint Position Statement on predatory journals, EMWA is providing a valuable service to publication professionals around the world by enabling them to more easily read, understand, and apply the principles of this JPS.

In order to raise awareness among non-English speakers about the responsibilities of medical writers and publication professionals concerning this significant issue, EMWA has initiated the translation of this statement into European languages.

We are proud to announce the posting of the first JPS translation into Greek by Theodoros Aslanidis and Alexandra Ingendoh-Tsakmakidis. In order to access the translation please click [here](#).

Armenian Translation of the Joint Position Statement on the Role of Medical Writers in the Preparation of Manuscripts for Publication

EMWA has been involved in the translation of the Joint Position Statement on the Role of Medical Writers. This statement was prepared together with our colleagues at AMWA and ISMPP in order to set out ethical standards for medical writers in developing scientific and medical publications. We are also spreading the word among non-native English speakers in Europe and beyond.

The position statement has now been translated into Armenian by Jack Aslanian and Mary A. Merark. It can be accessed [here](#).

You can read the statement in a variety of different languages by clicking on the relevant language tabs from the English language [Joint Position Statement page](#).

Pharmacovigilance Special Interest Group - News

- Detailed EMA guidance on Individual Case Safety Reports (ICSRs) in the context of COVID-19
- MHRA regulatory flexibilities resulting from COVID-19
- FDA's COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
- EMA: New testing and treatment recommendations for fluorouracil, capecitabine, tegafur and flucytosine
- No change is needed in use of direct oral anticoagulants following EMA-funded study
- Direct healthcare professional communication: Ulipristal acetate 5 mg for uterine fibroids not to be used during ongoing review of liver injury risk
- Webinar on the Guidance on the management of clinical trials during the COVID-19 pandemic on 15 May 2020 h 3:00-5:00 pm (EC / EMA / CTFCG of HMA). Webex will be recorded and made public
- EMA updated the Explanatory Note to GVP Module VII (Periodic safety update report)

To read more, please click [here](#)

Medical Device notified body updates

- Confirmation of MDR delay to the Date of Application
- New whitepaper on Sterilization - Sterilization – Regulatory requirements and supporting standards. Regulatory requirements for medical devices include particular requirements for devices supplied or intended to be used in a sterile state. These regulatory requirements have been supported by a portfolio of standards.
- Listen Back to a great webinar about the E.U. commission rolling plan and Eudamed; this also includes lessons learnt from the initial MDR audits.

Webinar Programme News

This month we are offering 2 webinars:

Thursday 14th May 2020, 14:00 CET - THIS WEBINAR IS OPEN TO NON-EMWA MEMBERS

Title: An update on the ICMJE recommendations

Speaker: Dr. Andrea Rossi, Freelance Medical Writer

Summary: The ICMJE is a small group of general medical journal editors and representatives of selected organizations working together to improve the quality of medical science and its reporting. The ICMJE has produced multiple editions of its recommendations, which were previously known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs) and continues to update them periodically. This webinar will cover the last update from December 2019 which included new guidance to improve the author's relationships and activities, the role of editorial advisory boards, the requirements for trial registration, the use of articles published on predatory journals, and Impact Factors.

Please register [HERE](#)

Thursday 21st May 2020, 14:00 CET

Title: The Rise of Coronavirus Diseases

Speaker: Sergey Sulima, Scientific and Medical Writer, BioNTech SE

Summary: The current global situation has sparked an increased interest in viruses, and particularly the coronavirus. This webinar will begin with a brief general introduction to virology, after which it will focus on the coronaviruses and the diseases they have recently caused (SARS, MERS). It will culminate with a discussion on the continuously growing body of information regarding SARS-CoV-2 and COVID-19, as well as pandemics in general.

Please register [HERE](#)

Changes to EMWA Freelance Directory

We recently made several changes to the layout of the [Freelance Directory](#) page, and members should now optimise their profile to obtain maximum search hits from potential new clients.

We encourage all freelance members to check whether their profiles accurately reflect experience and areas of medical writing in which they specialise. You should also add or update a profile photograph.

The new features include drop-down menus for the following categories:

- Language (select fluent language/s)
- Field of Expertise (Medical, Pharma, Scientific, Veterinary)
- Area of Expertise (Education, Technology, Scientific, Medical Communications; Medical Education; Regulatory)
- Specialist Services (Editing; Medical Devices; Medical Translation; Medical Writing; Proofreading, QA)
- Domain (select area/s of medicine you work in)

We hope our members will use this opportunity to highlight their skills, and that the updated and more comprehensive search criteria will better direct clients to the right person for the job.

Professional Indemnity Insurance - 20% Discount for EMWA Members!

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

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