TMQA Regulatory News Update July 2017

EMA Issues Guidance for Industry to Prepare for the UK's Withdrawal from the EU

The European Medicines Agency (EMA) and European Commission (EC) published guidance at the end of May 2017 to help pharmaceutical companies prepare for the UK's withdrawal from the EU. The guidance relates to both human and veterinary medicine and is in the form of a questions and answers document. It follows the publication of the EC/EMA notice to marketing authorisation holders (MAHs) of centrally authorised medicines for human and veterinary use on 2nd May 2017. This first list of questions and answers concerns information relating to establishment requirements within the Union (EEA) and answers questions such as what will happen to MAHs established in the UK, what will happen if Qualified Persons for Pharmacovigilance (QPPV) reside in and carry out their tasks in the UK, and what will happen if the manufacturing site of a finished product or active ingredient is located in the UK. The questions and answers will be further updated and complemented in the near future.

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228739.pdf

Highlights from EMA Management Board Meeting – June 2017

Highlights from the EMA's Management Board Meeting held in June 2017 have been published on the EMA website. The focus of this meeting was on Brexit preparations and the development of the EU clinical trial portal and database, which need to be fully validated before the new EU Clinical Trials Regulation can be implemented. An update on the EMA's preparation for the withdrawal of the UK from the EU was provided at the meeting. It is assumed that the UK will become a third country as of 30 March 2019. Preparatory work being carried out includes the following:

- Physical relocation of the EMA from London to one of the remaining 27 EU Member States. Impact assessments are being carried out to help prepare for the move, while retaining as many staff as possible. The decision on the EMA's new location is expected to be made by the European Commission in October 2017.
- Re-distribution of the workload – the Management Board endorsed principles and a working methodology to successfully undertake a (re)distribution of the workload relating to the evaluation and monitoring of medicines to ensure the high quality of the EMA's scientific assessments and compliance with legal timelines. The Board endorsed a mandate of two working groups, one focusing on human medicines and one focusing of veterinary medicines.
- Provision of guidance and information to pharmaceutical companies – the EU regulatory network wants to ensure that companies are ready to take the necessary steps to ensure undisrupted supply of their medicines. Guidance was published to help them review and adapt their processes and consider changes to the terms of marketing authorisations to ensure their continuous validity.

The progress made regarding the EU Clinical Trial portal and database was also discussed at the meeting. Due to technical difficulties with the development of the IT systems, the portals go-live date will be postponed. An update on progress will be provided at the next meeting in October 2017 but due to these delays, the EU Clinical Trial Regulation will now come into application in 2019 rather than 2018.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/06/news_detail_002764.jsp&mid=WC0b01ac058004d5c1

FDA Publishes Draft Guidance on Use of Electronic Records and Electronic Signatures in Clinical Investigations

The US Food and Drug Administration (FDA) issued a new draft guidance for industry in June 2017 titled "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11". The draft guidance is in the form of questions and answers and is intended to provide guidance to sponsors, clinical investigators, institutional review boards, contract research organisations and other interested parties on the use of electronic records and electronic signatures in clinical investigations of medicinal products under 21 CFR Part 11. It clarifies, updates and expands upon recommendations in the guidance for industry "Part 11, Electronic Records; Electronic Signatures – Scope and Application". The guidance also hopes to encourage and facilitate the use of electronic records and systems to improve the quality and efficiency of clinical investigations.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM563785.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

EMA Issues Concept Paper on Revision of the Guideline on Clinical Development of Vaccines

In June 2017, the EMA published a concept paper for public consultation on revision of the existing guidelines on clinical development of vaccines. The existing *Guideline on clinical evaluation of vaccines* was developed during 2005-2006 and came into operation in 2007. It covers the design of clinical development programmes for new vaccines that are intended to provide both pre- and post-exposure prophylaxis against infectious diseases. Some of the guidance is also relevant to the further development of licensed vaccines. Although much of the existing guideline is still fully relevant to current vaccine clinical development, a revision is proposed to address some issues that have come to light since it came into operation.

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/06/WC500229930.pdf

MHRA Updates Information on when a CTA is Needed

The MHRA updated information on their website relating to when a clinical trial authorisation (CTA) is needed. This was updated on 18 May 2017 and includes changes to clinical trial mock examples.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/614813/CTA_MOCK_Examples.pdf

Regulators Take Steps to Facilitate Development of New Antibiotics

The EMA, FDA and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) have agreed to align their data requirements for certain aspects of the clinical development of new antibiotics in order to stimulate the development of new treatments to fight antimicrobial resistance and protect global public health. Representatives from the three regulatory agencies met in April 2017, following an initial meeting in September 2016 at EMA where the agencies discussed regulatory approaches for the evaluation of new antibacterial agents. At this subsequent meeting the agencies discussed recommendations for the design of clinical trials that test new treatments for certain types of bacterial infections, including infections caused by multi-drug resistant organisms. They identified a number of areas where the data requirements in the three regions could be streamlined. The EMA, FDA and PMDA will be working to update their guidance documents.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/06/news_detail_002763.jsp&mid=WC0b01ac058004d5c1

New e-Learning Module on Reporting Suspected Adverse Drug Reactions Receives European Accreditation

A new e-learning module on the importance of reporting suspected side effects of medicines received European accreditation in June 2017. Doctors across Europe can now learn more about the importance of reporting suspected adverse drug reactions (ADRs) via a free e-learning module. Regulators, like the MHRA, rely on the reporting of suspected ADRs to make sure medicines on the market are acceptably safe. However, all reporting systems suffer from underreporting, and training healthcare professionals to report suspected ADRs is important to both raise awareness and help strengthen the system. The e-learning module has received the highest order of accreditation from the European Accreditation Council for CME (EACCME®). This means doctors are awarded one credit upon completion of the 45 minutes ADR e-learning module. The e-learning module was created by the Strengthening Collaborationfor Operating Pharmacovigilance in Europe (SCOPE) Joint Action Project.

https://www.gov.uk/government/news/new-scope-adr-e-learning-module-receives-european-wide-cmecpd-accreditation