Regulatory Round-up

February 2023

Also available on our new online news hub at

https://ct.catapult.org.uk/news-hub

EUROPE

European Commission (EC)

Quick guide for sponsors - Regulation 536/2014 in practice (Eudralex vol. 10)

The Clinical Trials Coordination and Advisory Group (CTAG) produced a quick guide for sponsors on the rules and procedures of the EU Clinical Trials Regulation to facilitate its implementation. This guide highlights specific legislation for clinical trials on Advanced Therapy Medicinal Products and important guidance and recommendations to take into account for clinical trials.

European Parliament votes to extend MDR transition period

The European Parliament voted for the extension of the transition period for the EU Medical Device Regulations (MDR) to avoid a shortage of life-saving products in the economic region and to extend the validity of certain device certificates.

The amendment comes after a 6 January vote on the same proposal was approved by the European Commission.

More information can be found here.

European Directorate for the Quality of Medicines (EDQM)

Public consultation on Ph. Eur. rabbit pyrogen test replacement texts

The European Pharmacopoeia (Ph. Eur.) has published the 59 texts (1 new general chapter, 5.1.13. Pyrogenicity, and 58 revised texts) concerned by the rabbit pyrogen test (RPT) replacement strategy for public consultation in Pharmeuropa 35.1, with a commenting deadline of 31 March 2023.

These texts, covering a variety of topics including vaccines for human use, blood products, antibiotics, radiopharmaceuticals and containers, have been revised to replace the RPT with an *in vitro* alternative, the monocyte activation test (MAT) or another animal welfare-compatible approach. More information can be found here.

Instructions on how to comment can be found here: Comment on drafts (Pharmeuropa).

Shutdown of European Pharmacopoeia 10th Edition

The European Pharmacopoeia (Ph. Eur.) 10th Edition has been obsolete since 1 January 2023. Consequently, the 10th Edition online and all previous versions,

including the Ph. Eur. archives for 10th Edition clients, have no longer been accessible since 31 January 2023.

The Ph. Eur. 11th Edition and its supplements are available to subscribers on the dedicated European Pharmacopoeia online platform.

United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA)

Impact of extension of Medical Device Regulations transitional period and the validity of certificates in the EU

The European Parliament has voted to adopt an extension of the transition period for the EU Medical Device Regulations (MDR). The changes made to the EU MDR will apply automatically to Northern Ireland under the terms of the Northern Ireland Protocol.

The MHRA is considering the implications of these changes for acceptance of CE marked medical devices on the Great Britain (GB) market. Currently a device with a valid CE mark can be placed on the GB market until 30 June 2023. There are plans to extend acceptance of the CE marking in GB which will be put into law in the coming months and the MHRA is to publish a guidance on this in due course. Please find more details here.

National Institute for Health and Care Excellence (NICE)

More than 400 people set to benefit after NICE approves ground-breaking CAR-T therapy to treat aggressive form of blood cancer

On the 26th of January 2023, NICE issued a final appraisal document recommending the treatment be made routinely available on the NHS for suitable patients.

People with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) who have had two or more lines of systemic therapy will now benefit from the first personalised immunotherapy treatment, Axicabtagene ciloleucel (Yescarta, Kite). More information can be found here.

USA

Food and Drug Administration (FDA)

Methods and Approaches for Capturing Post-Approval Safety and Efficacy Data on Cell and Gene Therapy Products

Ont the 27th of April 2023, the FDA's Center for Biologics Evaluation and Research (CBER) Office of Tissues and Advanced Therapies (OTAT) is hosting a virtual public

listening meeting to seek input on methods, approaches, logistics, privacy concerns, and other aspects related to efficacy and safety data collection in the post-approval setting for cell and gene therapies. Please find further details on this event, including how to register here.

Information for Practitioners - FDA's Regulatory Oversight of Regenerative Medicine Products

The FDA's Center for Biologics Evaluation and Research (CBER) hosted a public webinar on 17 November 2022 on the regulation of regenerative medicine products and its concerns about the proliferation of unapproved and potentially harmful products being marketed to patients. Recordings and minutes are now available here.

FDA CBER Office of Therapeutic Products (OTP) Advanced Manufacturing and Analytical Technologies (AMAT) for Regenerative Medicine Therapies (RMT) Workshop

On the 14th of March 2023, The FDA's Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) will host a virtual workshop for FDA staff and cell and gene therapy stakeholders to obtain specialised knowledge from experts in the field of advanced manufacturing and analytical technologies (AMAT) for regenerative medicine therapies (RMT), discuss innovative manufacturing technologies and alternative testing methods, and share experiences, challenges, and best practices critical for chemistry, manufacturing, and controls (CMC) of cellular and gene therapies and tissue engineered medical products. Please find more details on this event including how to register, here.

INTERNATIONAL

International Conference on Harmonisation (ICH)

ICH Q9 Quality Risk Management Revision 1: A Detailed Analysis

ICH Q9 (R1) guideline has reached stage 4 of the process as of 18 January 2023 and will become effective as of 23 July 2023.

The objectives of the revision were improvements in four areas:

- Subjectivity in QRM risk assessments and outcomes.
- Insufficient management of supply and product availability risks
- Lack of understanding of QRM formalities
- Lack of clarity about risk-based decision making

A detailed analysis of the implemented changes has now been published. For more detailed information please also see the revised ICH Harmonised Guidedline Quality Risk Management Q9 (R1) on the ICH website.

Public consultations

European Directorate for the Quality of Medicines (EDQM)

	Title	Consultation Period	Category
1.	*Public consultation on Ph. Eur. rabbit pyrogen test replacement texts*	*End date: 31 March 2023*	*Public Consultation*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	*Public meeting: FDA Rare Disease Day 2023*	*End date: 27 February 2022*	*Public consultation*
2.	*Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry*	*End date:14 March 2023*	*Draft guidance*

International Conference on Harmonisation (ICH)

	Title	Consultation Period	Category
1.	*ICH M11 Clinical Electronic Structured Harmonised Protocol (CESHARP)*	*End date: 26 February 2023*	*Public Consultation*

26 January – 25 February 2023