

Europe Legal and Regulatory Affairs

Watchdog Update



REGULATORY
WATCHDOG

This European watchdog is providing information relevant to ISCT areas of concern, including: 1) upcoming events (workshops, meetings...), 2) recently published regulatory documents, 3) public consultations and guidelines currently opened for comments and 4) follow-up on previously addressed events and 5) other topics.

1) No relevant new events

2) New EC acts on Good Manufacturing Practice

The European Commission adopted two legal acts concerning Good Manufacturing Practice, integrating principles and guidelines from Directive 2003/94/EC and Directive 2001/20/EC into Directive 2001/83/EC and Regulation 536/2014.

Details and the new acts can be found [here](#).

Commission Directive (EU) 2017/1572 mentions in the introduction (point 8, page 2) the upcoming GMP guideline for ATMPs referred in Article 5 of Regulation (EC) No 1394/2007.

Revised EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products

This is the first revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products'. It extends the existing EU guidance to address first-in-human (FIH) and early phase clinical trials (CTs) with integrated protocols.

The revision is intended to further assist stakeholders in the transition from non-clinical to early clinical development and in identifying factors influencing risk for new investigational medicinal products (IMPs). The document includes considerations on quality aspects, non-clinical and clinical testing strategies, study design and on conduct of FIH/early CTs. Strategies for mitigating and managing risks are given, including principles on the calculation of the starting dose to be used in humans, the subsequent dose escalations, the criteria for maximum dose, and the conduct of the trial inclusive of multiple parts.

The guideline applies to all new chemical and biological IMPs. While ATMPs are not within this scope, some principles of this guideline are relevant on a case-by-case basis.

The revised guideline can be found [here](#).

New ICH Guideline E18 on genomic sampling and management of genomic data

The main objective of this guideline is to provide harmonized principles of genomic sampling and management of genomic data in clinical studies. This guideline will facilitate the implementation of genomic studies by enabling a common understanding of critical parameters for the unbiased collection, storage, and optimal use of genomic samples and data. This guideline also intends to increase awareness and provide a reminder regarding subjects' privacy, protection of the data generated, the need to obtain suitable informed consent, and the need to consider transparency of findings in line with local legislation and regulations. This guideline is intended to foster interactions amongst stakeholders, including drug developers, investigators and regulators, and to encourage genomic research within clinical studies.

The new guideline can be found [here](#).

3) No relevant new public consultations

4) No relevant follow-up on previous events

5) Other topics:

EMA publishes comments on Member States' bids for EMA relocation

In view of the Agency's mandate to protect public health in Europe, EMA has undertaken a thorough analysis of the bids against the criteria agreed by the EU27. This is important to inform EMA's efforts to prepare for the move due to Brexit. To ensure the Agency remains operational and able to deliver on its mission after its relocation, the accessibility of the new seat for delegates and experts and staff retention are key, supported by adequate premises and facilities. EMA expects that the publication of this information will be useful for Member States when deciding on a suitable new host city and thereby ensuring that the Agency will be fully operational during and after its relocation. The decision on the new location by voting is scheduled for November 2017.

Details on the bids and the EMA evaluation can be found [here](#).

uniQure Announces It Will Not Seek Marketing Authorization Renewal for Glybera in Europe

The Marketing Authorization for Glybera[®] expires on October 25, 2017.

The full press release can be found [here](#).

New action plan to foster development of advanced therapies

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) have published a joint action plan to foster the development of advanced therapy medicinal products (ATMPs). The main aim is to streamline procedures and better address the specific requirements of ATMP developers.

The full text can be found [here](#).