International Society ISCT Cell & Gene Therapy
TELEGRAFT
MEMBER NEWSLETTER

Europe Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

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ISCT Legal and Regulatory Affairs Committee: Europe
Karolinska Institute
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CAT

CAT monthly report of application procedures, guidelines and related documents on recommendations on advanced therapy product classification: https://www.ema.europa.eu/en/documents/committee-report/cat-monthly-report-application-procedures-guidelines-related-documents-advanced-therapies-january_en-6.pdf

EDQM

Users of CEPs are invited to provide comments on draft monographs published in *Pharmeuropa* 32.2 before 30 June 2020. More information in document PA/PH/CEP (20) 17.

EMA

Read up on EMA's advice and initiatives regarding COVID-19 here: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19

Advancing regulatory science in the EU – new strategy adopted, read more at: https://www.ema.europa.eu/en/news/advancing-regulatory-science-eu-new-strategy-adopted

On March 27, 2020, Zolgensma (onasemnogene abeparvovec) got conditional approval from EMA. Zolgensma is a new gene therapy for the treatment of spinal muscular atrophy: https://www.ema.europa.eu/en/medicines/human/summaries-opinion/zolgensma

There is still time left to comment on the EMA reflection paper on GMP and Marketing Authorisation Holders: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-good-manufacturing-practice-marketing-authorisation-holders_en.pdf
Consultation runs from 17 January – 17 April 2020.