Regulatory & Pharma News Update October/November 2018

REGULATORY NEWS

Brexit Health Alliance Welcomes PM May's Draft Deal

The Pharmacy Business and Pharma Times revealed on 16th November 2018 that Brexit Health Alliance (BHA) backs the draft Brexit agreement approved on Wednesday by Prime Minister (PM) Theresa May's cabinet. The BHA brings together the National Health Service (NHS), medical research, industry, patients and public health organisations, its aim is to safeguard the interests of patients, the healthcare and the research they rely on during the Brexit negotiations.

The publications highlights that the BHA is pleased that under the new agreement there would be no tariffs on goods and those that were licensed before the transition period will continue to be circulated in the European Union (EU). The BHA also supported the guarantee that the existing rights of United Kingdom (UK) and EU citizens will be retained and that in the future will include appropriate arrangements for reciprocal professional qualifications. The proposed data sharing during the transition period with the aim of an agreement and declaration on continued co-operation on health security were also welcomed.

https://www.pharmacy.biz/brexit-health-alliance-backs-pm-mays-draft-deal/

http://www.pharmatimes.com/news/bha,_abpi_welcome_uks_eu_withdrawal_agreement_1260758

http://www.nhsconfed.org/brexithealthalliance

EMA Published a Report of Industry Stakeholder Meeting on Brexit and Operation of the Centralised Procedure for Human Medicinal Products

The report from the European Medicines Agency's (EMA's) on the 24th September 2018 meeting with industry stakeholders to discuss the UK's withdrawal from the EU and the impact on the operation of the centralised procedure for human and veterinary medicines was published on the 13th November 2018 and it outlines how the European medicines regulatory network is preparing for Brexit. This includes the EMA's relocation and business continuity planning. The meeting was organised by EMA together with the European Commission and was attended by a broad range of industry stakeholders. The report states that Stakeholders were reminded of the importance of adapting processes and making the necessary changes to the terms of the marketing authorisations in due time to ensure their continuous validity and exploitation, once the UK has left the Union.

A further three industry stakeholder meetings on Brexit are planned for 2019.

https://www.ema.europa.eu/en/news/emas-brexit-plans-ensure-agencys-focus-medicines-evaluation-supervision

https://www.ema.europa.eu/documents/report/report-industry-stakeholder-meeting-brexit-operation-centralised-procedure-human-medicinal-products_en-0.pdf

EMA: 'Working with Stakeholders to Improve Availability of Medicines in the EU'

A two-day workshop (8-9th November 2018) was organised by the EMA and the Heads of Medicines Agencies (HMA) to gather stakeholders' perspectives on how to avoid shortages of medicines. The publication released by the EMA on 31st October 2018 states that improving the availability of human and veterinary medicines authorised in the EU is a key priority of the European medicines regulatory network. The aim was to improve continuity of supply of human and veterinary medicines across Europe. In the context of the potential supply disruption of medicines following the UK's withdrawal from the EU, the task force serves as a platform to facilitate and coordinate actions between Member States, EMA and the European Commission.

https://www.ema.europa.eu/en/news/working-stakeholders-improve-availability-medicines-eu

UK Seizes More Than £2 Million of Fake Medicines

In October the Medicines and Healthcare products Regulatory Agency (MHRA) and UK partners found falsified and unlicensed medicines and medical devices in the UK including diazepam, modafinil and dermal fillers which was more than 1 million doses in total. The seizures were part of Interpol's globally coordinated Operation Pangea initiative involving 116 countries. Worldwide, Operation Pangea led to 859 arrests and yielded items worth in the region of £10.9 million. Websites on the open and dark web that offer falsified and unlicensed medical products also were targeted, which has led to 123 websites being shut down and 535 online adverts being removed.

https://www.gov.uk/government/news/uk-seizes-more-than-2-million-of-fake-medicines-as-part-of-international-crackdown

The New GVP Chapter IV was Published by the EMA for the Paediatric Population

The publication dated 13th November 2018 states that new good pharmacovigilance practice (GVP) chapter IV on specific considerations for the paediatric population offers a holistic view of paediatric pharmacovigilance and provides guidance on how to make best use of existing tools and processes to address the specific needs and challenges of safety monitoring of medicines used in children and also advises on how to adapt regulatory requirements to the paediatric population in the EU. The new GVP chapter replaces EMA's Human Medicines Committee's (CHMP) 2007 guideline on conduct of pharmacovigilance for medicines used by the paediatric population.

https://www.ema.europa.eu/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-iv_en-0.pdf

https://www.ema.europa.eu/en/news/ema-gives-guidance-safety-monitoring-medicines-used-children

FDA Released Plant and Animal Biotechnology Innovation Action Plan

The Plant and Animal Biotechnology Innovation Action Plan announced on 30th October 2018 provides an overview of priorities the Food and Drug Administration (FDA) will pursue to support innovation in plant and animal biotechnology and to advance the FDA's public health mission.

It is stated in the publication that The Action Plan identifies concrete priorities in three key areas:

- Advancing public health by promoting innovation
- Strengthening public outreach and communication
- Increasing engagement with domestic and international partners

FDA plan to adopt a comprehensive policy framework for the development and regulatory oversight of animal biotechnology products, including for intentionally genetically altered animals and the food and drug products derived from them. As a part of this initiative, the FDA intends to publish two guidance documents over the next year.

FDA also announced Public Webinar on Genome Editing in Animals, which is planned for the 3rd December 2018 (the webinar description says that it will focus primarily on the current science, promising uses of this technology in animals, and the potential risks) and the Veterinary Innovation Program (VIP). The VIP program is for certain intentionally altered genomic DNA in animals (intentionally genetically altered or IGA animals) and animal cells, tissues, and cell- or tissue-based products (ACTPs) seeking FDA approval of a new animal drug application (NADA).

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624541.htm

https://www.fda.gov/Safety/Biotechnology/ucm624416.htm

https://www.fda.gov/downloads/Safety/Biotechnology/UCM624517.pdf

https://collaborationcqpub1.fda.gov/content/connect/c1/7/en/events/event/shared/94473679/event_landing.html?sco-id=157630107&_charset_=utf-8

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm620835.htm

FDA Proposes First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs

The FDA is re-launching a Drug Competition Action Plan for 2019 with some additional initiatives. Drug Competition Action Plan focuses on three key areas designed to facilitate more generic competition, promote patient access, and improve the economics of developing generic medicines. The main initiative, as stated in the publication by FDA Commissioner Scott Gottlieb, M.D., is a new effort that FDA has proposed to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH): The pursuit of common global development standards for generic drugs.

The publication highlights that the ultimate goal of this global harmonization of scientific and technical requirements would be the attainment of a single global generic drug development program that can support simultaneous regulatory filings across multiple markets. Harmonization of these requirements is foundational to achieving a future goal of enabling global approval for high quality generic drugs.

The article expounds which important benefits can potentially be brought by the harmonization of scientific and technical standards.

https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm623665.htm

PHARMA NEWS

EMA: EU Authorities Take Further Action in Ongoing Review of Sartans

The EU authorities will supervise the manufacture of other active substances produced by Zhejiang Huahai Pharmaceuticals (ZHP) more closely following detection of an impurity. In July 2018, EMA released news on some valsartan medicines being recalled across the EU after the company detected an impurity, N-nitrosodimethylamine (NDMA) and and N-nitrosodiethylamine (NDEA) (which are classified as a probable human carcinogens). As a result of inspection of the ZHP, a statement of non-compliance for the manufacture of valsartan has been issued by the EMA and the site is no longer authorised to produce valsartan (and its intermediates) for EU medicines.

The EMA announced on 15th October 2018 that they will monitor corrective measures being implemented by the ZHP on a regular basis and increase the frequency of inspections of the site. Marketing Authorization Holders for EU medicines will be required to perform additional tests on all active substances supplied by the ZHP.

The publication released by EMA on 15th October 2018 states that low levels of NDEA have now also been found in a third sartan, irbesartan, made by another Indian company, Aurobindo Pharma. On 8th October 2018, the European Directorate for the Quality of Medicines & HealthCare (EDQM) suspended Aurobindo Pharma's CEP (certificate of suitability to the monographs of the European Pharmacopoeia) effectively stopping the supply in the EU of medicines containing irbesartan from this company.

National authorities in the EU are considering whether to recall medicines containing Aurobindo Pharma's irbesartan from pharmacies as a precaution.

The review into the presence of impurities in sartans and their potential effects in patients is ongoing and is evaluating candesartan, irbesartan, losartan, olmesartan and valsartan, which belong to a class of medicines known as angiotensin-II-receptor antagonists.

As published by EMA on 19th November 2018, authorities in the EU are also taking action after NDEA was found in some batches of valsartan made by Mylan Laboratories Limited in Hyderabad, India. The EDQM has now suspended the manufacturer's CEP, effectively prohibiting the use of its valsartan in EU medicines. In addition, national authorities in the EU have started recalling affected batches of medicines containing Mylan's valsartan and are conducting further tests to determine the extent of the contamination.

https://www.ema.europa.eu/en/news/eu-authorities-take-further-action-ongoing-review-sartans-zheijiang-huahai-placed-under-increased

https://www.ema.europa.eu/en/news/valsartan-mylan-laboratories-india-can-no-longer-be-used-eu-medicines-due-ndea-impurity

FDA: Updates on Valsartan Recalls

Following a recent inspection at ZHP's facility, the FDA placed ZHP on import alert in September 2018, which stops all active pharmaceutical ingredient (API) made by the company and finished drug products made using ZHP's API from legally entering the United States (US). The action was taken to protect US patients while the API manufacturer fully determines how impurities were introduced into its API and remediates its quality systems. In addition, the FDA released on 10th October 2018 a method for detection and quantification of both NDMA and NDEA.

https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm

EMA: First Vaccine for Prevention of Dengue

The publication released on 19th October 2018 states that the EMA's CHMP has recommended granting a marketing authorisation for Dengvaxia (dengue tetravalent vaccine (live, attenuated)), for the prevention of dengue caused by dengue virus serotypes 1, 2, 3 and 4 in people who are between 9 and 45 years old, live in an endemic area and already had a prior dengue virus infection.

https://www.ema.europa.eu/en/news/first-vaccine-prevention-dengue

PharmaTimes: 'MPs voice concern over clinical trials transparency'

'PharmaTimes online' released news on 31st October 2018 (by Selina McKee) about the expressed concern by MPs that nearly half of clinical trials in the UK fail to publish their results, "presenting risks to human health and increasing research wastage". The article provides the following data referring to the trials tracker website: Public Health England has three overdue trials dating from 2010-2016 relating to meningitis vaccination; NHS Trusts have high numbers of unreported clinical trials: the Manchester University NHS Foundation Trust has 13 overdue trials, NHS Greater Glasgow and Clyde has 12 that are due to have reported, and both Newcastle upon Tyne Hospitals NHS Foundation Trust and Hull and East Yorkshire Hospitals NHS Trust have 11 outstanding trials.

http://www.pharmatimes.com/news/mps_voice_concern_over_clinical_trials_transparency_1257847?utm_source=PT%20Daily%20Newsletter&utm_medium=email&utm_campaign=pt%20daily%20news%20alert&