



Issue 6 - December 2019

HemAffairs holds your regular dose of policy, regulatory and pharma news with impact on hematology in Europe. We also keep you abreast of relevant publications and events to keep an eye on. Enjoy the read.

We are always eager to grow the hematology savvy community and are very happy with you forwarding HemAffairs to individuals and organisations in your network with an interest in the news we share. They can subscribe to this newsletter and from then on be part of our mailing list, in full respect of data protection and privacy. All they need to do is email us at communication@ehaweb.org.

Better regulation

Better regulation is one of EHA's key priorities in engaging with policymakers and regulators at the international level. The two lead articles of this HemAffairs issue offer examples of such engagement. 'Better' regulation does not, by definition, mean more regulation. Or less. New EU rules can be extremely valuable if the result is more harmonization, improved patient (or donor) safety and fewer obstacles to innovation. What is crucial however, as both articles will show, is regulatory clarity and consistency: uniform definitions and uniform, unambiguous interpretation of the rules.

The past and future of the EU Blood, Tissues and Cells legislation



The European Commission [recently concluded](#) that the Blood, Tissues and Cells (BTC) Directives have been effective in enhancing safety. Nonetheless, there is room for improvement on quality standards and efficacy. As EU stakeholders gathered to review the challenges and solutions on October 28, 2019, EHA zoomed in on the views of hematologists with Prof. Anneke Brand, Professor Emeritus of Transfusion Medicine of the Leiden University (The Netherlands).

[Read more...](#)

Revising the ICH Guidelines on Clinical Trials



Clinical trials and drug development have become more complex over the years. One complicating factor is the increased administrative burden. While the EU is turning to the implementation of the new Clinical Trials Regulation (CTR), the ICH has been working on a revision of its 1997 'Guidelines for Clinical Trials'. The EHA representatives provided input for the new guidelines during a stakeholder meeting.

[Read more...](#)

Shortages



Survey on medicine shortages

The European Association of Hospital Pharmacists (EAHP) is conducting a survey on medicine shortages targeted at all healthcare professionals working in the hospital environment, as well as patients. It collects information about the causes and impact of shortages, and seeks to identify solutions and best practices. The survey, which closes on January 13, 2020, can be found [here](#).

EMA-HMA guidance for authorization holders and regulators

In early 2020, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) will begin implementing [guidance](#) for marketing authorization holders on the reporting of medicine shortages. Another guidance has recently been published on [communication to the public](#) about availability issues, and intended for the national competent authorities and EMA itself.

EMA Working Parties

EHA and fellow members of the EMA Health Care Professionals Working Party (HCPWP), together with the Patients and Consumers Working Party (PCWP), have consistently been bringing availability issues to the attention of the regulators. For more information, see the joint [HCPWP-PCWP Work Plan 2019-2022](#), to which EHA contributed actively.

Regulatory news

European Medicines Agency

Positive opinions

New medicines

Polivy (polatuzumab vedotin): Polivy is intended for the treatment of diffuse large B-cell lymphoma (DLBCL), in combination with bendamustine and rituximab – **ORPHAN MEDICINE**

Tavlesse (fostamatinib): Tavlesse is intended for the treatment of primary immune thrombocytopenia (ITP).

Generics

Clopidogrel/Acetylsalicylic acid Mylan (clopidogrel/acetylsalicylic acid): Clopidogrel/Acetylsalicylic acid Mylan is intended for the secondary prevention of atherothrombotic events

Deferasirox Accord (deferasirox): Deferasirox is used for the treatment of chronic iron overload due to blood transfusions in patients with beta thalassemia and other anaemias

Authorizations

New market authorizations

Xospata (gilteritinib): EMA's CHMP authorized Xospata used to treat adults with acute myeloid leukaemia (AML) – **ORPHAN MEDICINE**

Generics

Arsenic trioxide Accord (arsenic trioxide), used to treat acute promyelocytic leukemia (APL).

Bortezomib Fresenius Kabi (bortezomib), used to treat acute multiple myeloma.

Ivozall (clofarabine), used to treat acute lymphoblastic leukemia.

Withdrawal

Luxceptar (viable T-cells): Kiadis Pharma withdrew its application for a marketing authorization of Luxceptar intended for the treatment of patients with blood cancers who are receiving a type of blood stem cell transplant.

European Commission



Rules governing medicinal products in the EU

The Commission released a [draft Questions and Answers](#) on the application of the Clinical Trials Regulation (EU). The document is meant as a guidance for healthcare professionals on the new requirements, compared with the former Clinical Trials Directive.



Guidelines on good clinical practice (GCP)

The Commission published the [Guidelines on Good Clinical Practice \(GCP\)](#) specific for Advanced Therapy Medicinal Products (ATMP). Compliance with good clinical practice is mandatory for clinical trials conducted in the EU. The guidelines do not apply to trials with medicinal products other than ATMPs.

Policy news



The brief – Ursula: Year one

On November 27, the European Parliament accepted [Ursula von der Leyen's Commission](#) by 461 votes to 157. The Commission took office on December 1, 2019, a month later than planned. Its working plan for 2020 is expected in the coming days.



Digital solutions can make healthcare easier and more equitable

In an [interview](#), Andrzej Rys, the European Commission's Director responsible for health systems, medical products and innovation at the Directorate-General for Health and Food Safety (DG SANTE), explains his vision on the digitalization in healthcare.

Pharma news



EU Regulations are holding back gene and cell therapy clinical trials

According to a study by the Alliance for Regenerative Medicine, a global industry-led advocacy collective, in the past four years, the [number of clinical trials with advanced therapies has stalled in Europe](#), growing by just below 2%.



Alexion to acquire Achillion

[Pharmaceutical company Alexion](#) announced it has entered into a definitive agreement to acquire Achillion, a clinical-stage biopharmaceutical company, focused on the development of oral small molecule Factor D inhibitors to treat immune-related rare diseases.

Meetings

[Educational Conference for nurses and other health care professionals](#)

Organized by the Haematology Nurses & Healthcare Professionals Group

January 10-11, 2020

Zürich, Switzerland

[25th Congress of EHA](#)

Organized by EHA

June 11-14, 2020

Messe Frankfurt, Germany

[2nd European CAR T Cell Meeting](#)

Organized by EHA and the European Society for Blood and Marrow

Transplantation

January 30 - February 1, 2020

Sitges, Spain



EHA | Towards a cure for all blood disorders
The European Hematology Association (EHA) promotes excellence in patient care, research and education in hematology. EHA envisions a world without blood disorders by connecting hematologists worldwide, supporting their career development and research, harmonizing hematology education and advocating the interests of hematology and hematologists in the European arena.

EHA Executive Office
Koninginnegracht 12B
2514 AA The Hague, The Netherlands
T: +31 (0) 70 3020 099
W: www.ehaweb.org | E: info@ehaweb.org

EHA | POWERED BY YOU!



EHA, Koninginnegracht 12b, 2514 AA, The Hague, Netherlands

You may [unsubscribe](#) or [change your contact details](#) at any time.