Dear reader,

We are happy to present the first issue of HemAffairs, your monthly dose of policy, regulatory and pharma news with impact on hematology in Europe. HemAffairs will bring you a selection of EU news – legislation, funding opportunities, consultations and drug approvals – as well as concise information about market developments, policy debates, projects and collaborations. It will also alert you to relevant EHA and stakeholder meetings and publications. We hope you will find it useful.

Share your comments via communication@ehaweb.org.

Every European citizen should have access to the best quality medical care at the best possible price. Pan-European cooperation on HTA is an essential step towards achieving this. EHA therefore supports the European Commission's proposal for a Regulation on HTA and is looking forward to a political agreement on the text. What is the current status of joint HTA? What are the plans of the Romanian presidency of the EU?

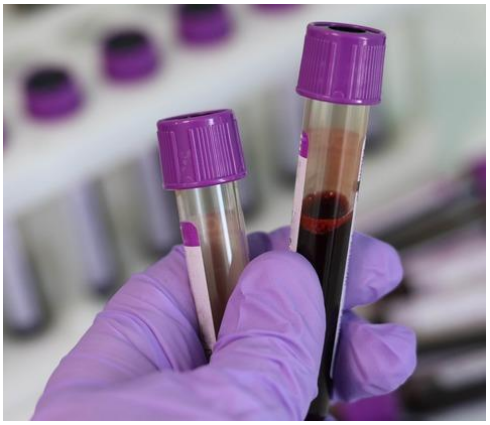
Read more...

Speeding up CAR T uptake in Europe

Gene (editing) therapy continues to break ground in hematology, showing promising results in tackling severe blood cancers. Yet, its uptake in the European Union is slow, with few patients benefiting from it so far. EHA advocates for greater support to gene therapy in upcoming EU health-related funding programs to address lingering obstacles.

Read more...

GAPP Joint Action



Joint Actions are projects designed and financed by Member State Authorities and the EU to address specific priorities under the EU Health Program. They contribute to solving problems at the European level. FacilitatinG the Authorisation of Preparation Process for blood, tissues and cells is the focus of the GAPP Joint Action, which launched in 2018.

Learn more about GAPP.

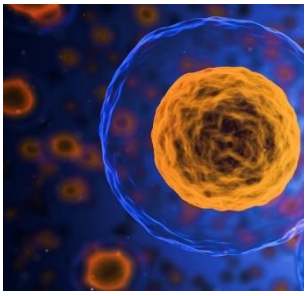
Regulatory news

New indication for Blincyto: The marketing authorisation for Blincyto, for the treatment of acute lymphoblastic leukemia (ALL), was amended and now includes: “Blincyto is indicated as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%”.

UK recommendation for Novartis' CAR T Kymriah for lymphoma:
The UK's National Institute for Health and Care Excellence (NICE) expanded the scope of its recommendation for Novartis' Kymriah (tisagenlecleucel) to be covered by the Cancer Drugs Fund. Besides for ALL in children, the CAR T therapy is now also advised for adults with diffuse large B-cell lymphoma.

Pharma news

Competition for affordable and innovative medicines.
The European Commission concludes that proper enforcement of competition law in the pharmaceutical sector contributes to delivering more affordable, innovative medicines. DG Competition's report on the 9-year investigation was released on January 28, 2019.



EUSA Pharma buys rights to Janssen rare disease drug.
The company has bought the rights to Janssen's orphan drug Sylvant and intends to develop it for better patient access worldwide. It is the only approved treatment for multicentric Castleman's disease in many countries. Less than 2,000 patients are affected in Europe.

Hematology H2020 calls for proposals - now open!

Regenerative medicines: From new insights to new applications. Aiming to address the unmet needs of large patient groups, this call focuses on the development of therapies for regenerating human cells, tissue or organs.

Support for the International Consortium for Personalised Medicine. Projects should aim for inter-regional cooperation and collaboration with third countries to enhance knowledge transfer on personalised medicine.

Univocal identification of medicinal products. Names, strengths and packaging sizes may differ for the same medicine from one country to the next. This call aspires to harmonize patients' cross-border mobility.

Publications

The **World Federation of Haemophilia (WFH)** published the key conclusions of its first round table meeting on gene therapy. The event aimed to kick-start global dialogue on the challenges and opportunities of disruptive treatments for hemophilia patients. Read more in the official journal of WFH.

The **European Public Health Alliance (EPHA)** has presented its annual analysis of biggest issues in medicines policy.

Meetings

EU grant proposal writing and management
Organized by the PROFILE Innovative Training Network
April 4, 2019
Copenhagen, Denmark

24th European Hematology Association Congress
Organized by EHA
June 13-16, 2019
Amsterdam, The Netherlands