

Final Conference of GAPP Joint Action

Establishing standards, and harmonising practices and treatments across the EU in the field of Blood, Tissues and Cells (BTC) - The impact for donors and recipients

Scientists and policy-makers meet on **January 20th and 21st 2022** for the final dissemination conference of the **GAPP Joint Action**. This meeting is organised in hybrid format, remotely as well as in Thessaloniki Greece. [GAPP](#) (facilitatinG the **A**uthorisation of **P**reparation **P**rocess) for blood, tissues and cells, is a 45month EU Joint Action co-funded by the European Commission under the EU Health Programme.

The high-level event brings together **24** beneficiaries, from **16** EU Member States and **2** non-EU countries, from EU Institutions, BTC Competent Authorities Tissue Establishments, scientific societies and accreditation bodies, healthcare professionals. Experts in the field and representatives from patient and donor organisations, have been invited to take part to the event as relevant stakeholders.

Day one of the event provides an overview of the work carried out at the EU level. **Day two** looks into bridging the gap between science and effective policies. On day two, participants also take a closer look at governance, the current state-of-play and the next steps. The **final objective** is the implementation of policy on BTC to ensure **EU-wide safety for patients and donors**, as well as a **high quality of BTC treatments**.

***Stefaan van der Spiegel, Head of Sector, Substances of Human Origin, European Commission - DG SANTE** said: “The GAPP Joint Action has provided a stepping stone for the upcoming [revision](#) of the legislation on Blood, Tissues and Cells, which the European Commission plans to adopt in the coming months. This work brings greater assurance when receiving safe and effective treatments. The result is more harmonized healthcare for patients and donors across the EU, with standardized procedures and processing protocols, that will be better aligned with the rapid, high-level and dynamic scientific and technological development of the field.*

*The **new EU framework** will bring better and more up-to-date **safety and quality** standards, facilitate **innovation** and allow for better **access to BTC therapies**. The new common framework will allow for more smooth **cross-border exchanges of BTC**, and the availability of **services and novel products or treatments** to EU citizens. The initiative extends also strengthens **donor protection and donor care**.”*

GAPP JA Coordinators said: “GAPP JA deliverables should be considered as an important milestone that improves preparation practices, and eventual outcome for BTC recipients across Europe. The Action introduces the use of clinical data within the authorization procedures” – **Massimo Cardillo, Italian National Transplant Centre Director**.

*“The GAPP Action also identifies the need for **up-to-date guidelines** based on the evolution of research, therapeutics and information technology, while it lays down the foundations of **a central knowledge sharing platform** at an EU level which can be updated, easily accessible and transparent.” – **Vincenzo De Angelis, Italian National Blood Centre Director***

During these past years, important work has been done by experts and CAs at the EU level, through the Joint Action. Members worked towards:

- providing EU CAs with the tools for the **standardisation** and **harmonisation** of processes across EU Member States.
- a uniform approach for **patient safety**
- ensuring **quality** of BTC used for transfusion, transplantation or medically assisted reproduction and improving the **effectiveness** of **practices** and **treatments** for recipients
- the **revision** of the EU legislation on BTC and the **implementation** of Union legislation

One durable output of the GAPP JA is a concept model for a **knowledge sharing platform** that can facilitate information sharing in the EU and supports the CAs in the assessment and evaluation of novel preparation processes of BTC (PPAs). Furthermore, the Action has already organised **a free 3-month Advanced Training Course** consisting of 7 modules on ‘Common Approaches to PPA Authorisation in the blood tissues cells, and MAR sectors’ addressed to European experienced inspectors and assessors, including **e-learning platform** and **virtual live sessions**. So far, nearly **forty experts** from the EU MS CAs have been successfully trained by the Action. The aim is to train as many as CAs inspectors/assessors as possible, and therewith develop an international network of experts that can support CAs when evaluating new preparation process authorization.

Notes to Editors:

[About GAPP JA infographic](#)

GAPP JA [Position Statement infographic](#)

GAPP [two-minute video](#)

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