

Heraklion, 12 December 2018

To:
The Danish Health and Medicines Authority (DHMA)

Dear Colleagues,

As you know, Joint Actions are projects designed and financed by Member State Authorities and the EU to address specific priorities under the EU Health Program. They have a clear EU added value as they are expected to contribute to solving problems at the European level, and to have a greater impact than single national activities, especially at policy making level.

GAPP is the acronym (Facilitating the Authorisation of Preparation Process for blood, tissues and cells) of a new Joint Action which launched in May 2018 with 36 months duration (<https://www.gapp-ja.eu/gapp-ja/>). The main aim of GAPP is to facilitate the development of a common and optimal approach to assess and authorize preparation processes, in Blood and Tissues Establishments adapting requirements as prescribed by Article 29 of Directive 2002/98/EC and Article 28 of Directive 2004/23/EC. GAPP will give particular attention to innovative processes under development and/or previously described in relevant EU Joint Actions.

The main objectives of GAPP are:

- 1) To increase the consistency and efficacy of Competent Authority (CA) regulatory activities through harmonization of EU-level tools for authorization procedures for preparation processes at blood and tissues establishments.
- 2) To develop a concept model for a European knowledge-sharing platform that can support CAs in the assessment and evaluation of novel preparation processes of products.
- 3) To develop an international network of experts that can support CAs in the assessment and evaluation of preparation processes of products, trained by the Joint Action.

GAPP is coordinated by the Italian National Institute of Health, National Transplant Centre, and National Blood Centre and includes 17 European countries and more than 40 partners.

In an attempt to disseminate the information on GAPP activities we kindly ask you to provide us contact information of possible stakeholders in your country that might be interested in GAPP objectives. Therefore, we kindly ask you to fill the attached file and send it back to us by **January 15th**.

Thanking you in advance,

On behalf of the GAPP Dissemination Team,



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