EUROPEAN BLOOD ALLIANCE

EBA submission on the European Commission's proposal for a European Health Data Space (EHDS)

Submitted on 26 July 2022

The European Blood Alliance (EBA) welcomes this proposal on the European Health Data Space (EHDS). European blood establishments represented by EBA have regularly asked for more and better data to increase donor protection and reinforce patient care; we believe that the EHDS can be a fundamental tool in working towards these goals.

EBA has been calling on the EU and Member States to reinforce donor vigilance requirements through a pan-European donor vigilance programme. We believe that the reporting of data on Substances of Human Origin (SoHO) should be further developed and that such systems should provide public access to key anonymised data on European registries, including clinical follow up, which would support enhanced transparency on donor health. EBA has also called for data across the EU to be pooled, in full compliance with the General Data Protection Regulation (GDPR). Allowing researchers and clinicians access to these registries would be an incentive to improve their reporting and enable practitioners to evaluate the efficacy of SoHO safety measures. EHDS should provide the basis for this work.

EBA is pleased that the new Commission's proposal for a Regulation on substances of human origin also goes in this direction and we urge legislators to ensure both EHDS and the SoHO Regulation are well aligned in this respect.

There are many examples of how pooling this data across Europe can enable enhanced protection of both donors and recipients. For example, as Europe works to limit its dependency on third countries for human plasma to develop plasma derived medicinal products (PDMPs), it is extremely important to understand the long-term effects of plasma donation, particularly in situations where frequency is increased. There are also several studies trying to understand possible transfusion-transmission of certain rare conditions through donations, such as cerebral amyloid angiopathy (CAA). To be conclusive and verified, these studies rely on a 'big-data' approach to hemovigilance with the use of data from electronic healthcare records and health registers. EBA would like to stress that for EHDS to be a useful resource in this respect, it must include methods to unambiguously identify and trace individuals (donors or transfused patients) as they come in contact with the health care system throughout the rest of their lives.

Despite the potential of the EHDS, EBA also has some concerns regarding the proposal in its current state. Future implementing and delegated acts must ensure that EHDS does not become a burden to healthcare professionals in general and workers in blood establishments in particular.

EBA is also concerned about the interplay with other EU legislation, such as GDPR. From our experience in the EU-funded SUPPORT-E Project, which supports a high-quality evaluation of COVID Convalescent Plasma (CCP) throughout Europe, many countries have varying regulations regarding

data sharing and the definition of anonymised data. This blocked many countries from sharing their data on the EU CCP Database and was only minorly resolved when an official statement from the EU was issued. However, some countries, such as Denmark, were still unable to publish their data.

Finally, EU legislators should ensure that EHDS-related measures are compatible with the digital infrastructure and capacity in Member States, or foresee the resources and time required to set those in place.

Blood establishments play a central role in the supply of blood components and are therefore crucial players in a high-performing and resilient European health system. We urge EU legislators to establish forms of regular dialogue with blood establishments to ensure that the EHDS architecture becomes a tool for both better donor vigilance and patient safety while avoiding adding complexity to an already challenging environment.
