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EBA's answer to EC consultation on the creation of HERA
(submitted online, through the EC "have your say" website)

The European Blood Alliance (EBA) agrees with the context, problems, issues and objectives identified in the Inception Impact Assessment (IIA).

The EBA highlights that the EC response must be flexible and generic for all major crisis not just pandemics. The risks to the EU and its member states of not having a safe and sustainable blood supply is life threatening.

Blood and Blood Components (BABC) are the lifeline of the European healthcare system. Without it people will die. A safe and sustainable blood supply is a basic human right for every European citizen.

All EBA member were directly impacted by COVID-19 via their day-to-day operations, their ability to provide possible solutions (e.g. Convalesent Plasma, the development of Hyper immune products), and their capacity to provide urgent testing, quickly and on mass. Blood Establishments (BE) in the EU already contribute to surveillance depositories and emerging viruses.

EU funding for R + D in these areas is critical. There are risks inherent to open and free trade to the EU and Member States of not recognizing or regulating the supply of outsourced critical material in time of acute need. EU legislators must ensure the EU can scale up vital supplies of certain products e.g., vaccines and PPE ensuring supply to all member states is fast, equitable, fair and efficient. EU members different lockdowns and internal travel restrictions caused BE major challenges re. donors attending clinics, clinic venue availability and BABC supply contingencies becoming vulnerable. EU legislators must recognise and support European Blood Establishments to ensure supply of BABC in times of crisis.

Furthermore EBA can assist the EU to prepare better for future crisis. EBA supports the creation of a Europe of health that will be based on the capacity to respond to and cope with future pandemics in a spirit of solidarity, but also on better coordination of preventive actions and the search for industrial autonomy in the field of health.

On the 4 suggested policy options:

The EBA favours the creation of a stand alone authority (HERA) as described in option 2 able to act on decisions quickly. The sub-options as currently described are incomplete solutions, both must be realistic and need more elaboration. The EBA reasserts the importance of individual EU members maintaining the right (legislation) to act at a regional, and national level to respond to such crisis on an individual basis if necessary. Contingency planning and crisis preparedness are already successfully performed by many EU members.

Option 0 : An adhoc (unprepared) solution with limited input from the Health programme will not deliver an effective crisis response for all member states.
Option 1 : The coordination describe brings an added value but it should be done under the supervision of a permanent authority and not the EC.

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Sub- option 2.1: The scope, role and tasks of HERA should be well defined, especially when it comes to its interaction with other EU agencies e.g. ECDC and EMA. Stockpiling of medical products and PPE, the development of joint public procurement and research and innovation policies must be a high priority to ensure our preparedness for future pandemics. However, smart stockpiling is key as there are complexities of stockpiling specialist products for EU members involving - different quality standards / specifications, expiry dates, FIFO, product recall, narrowing – interfering with the free market. Complicated logistical requirements must be identified and resolved.
Sub- option 2.2 In addition to all the above, further clarification on the scope and the meaning of "access network" are required. Option 3 The EBA believes this option is workable but as it stands it could be too autocratic and inflexible. Further clarifications on who decides when a crisis is ongoing and where actions are are needed.