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EBA agrees with the gaps and issues identified in the **first part of the IIA** and highlights the following:
Reliance on third countries on plasma for PDMPs is in part due to off-label non-evidence-based use. The EU needs to support more research on efficacy of the plasma-based products for a number of diseases while Member States (MS) need to increase their plasma collection from the not-for-profit sector.
EBA strongly supports the principle of voluntary unpaid donation (VUD). Although the EU should respect MS' competence, VUD, being a fundamental notion, should not be left entirely up to MS. EBA urges EU legislators to maintain it in the next texts. Leaving the choice to MS on whether or not to implement VUD would deny the very concept of a **common** European framework. The EC should promote and support activities which would increase plasma donations from VUD donors. On the evidence available one cannot conclude that potential shortages of supply are due to VUD.

On the 4 policy options
Blood is not a commodity and its specificities should not be dealt with through the ECJ. It should be legislated for at EU level based on Public Health principles and not on internal market ones irrespective of its end use.
EBA favours Policy option 2 as the best solution. The role and tasks of ECDC and EDQM should be well defined. Strengthening oversight and audit by the EC are welcomed as per option 1 but must be realistic and performed by experts in the field. EBA supports a change in the scope of the BTC legislation in terms of clarity and increased flexibility and to include novel substances of human origin both those currently used in an unregulated fashion, as well as new ones coming on line. EBA reasserts the importance of VUD while reviewing novel substances of human origin.
EBA welcomes the proposal to strengthen donor vigilance, in particular in reporting adverse reactions and ensuring more donor protection. However, the latter should not be confused with testing donors, in particular in the tissues and cells sector.
Contingency planning and crisis preparedness, mostly through a constant monitoring of supply and demand, is already performed at national level even in the context of COVID-19. A pan-European central hub for data pertaining to supply and demand would be welcomed*. Support by the EC to allow IT systems interoperability would help in reaching this goal.
Policy option 1 will not support cross-country harmonisation and trust, which could be a source of an inhomogeneous situation in the EC. The option will be difficult to implement for smaller countries. It could also generate heavy bureaucracy and reporting duties.
Policy option 3 is similar to the existing legislative framework which proved to be too slow and not flexible enough. The role of the comitology would be a duplication of the EDQM and ECDC; it would call for additional costs and resources.
Combining policy options would require very robust definitions. On the basis of experience acquired with COVID-19 Convalescent Plasma, in circumstances where an acute novel response is required, the EC should only make recommendations on minimum requirements and not enforce strict binding technical rules as these may eventually fall foul of emerging evidence.

On the preliminary assessment of expected impacts
EBA supports the analysis on likely economic and social impacts, underlining the importance of donor protection, although option 1 risks increasing inequalities on the latter.

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When addressing likely impacts on fundamental rights, the legislators must bear in mind VUD and non-discrimination principles for all donors. Donor selection should be made on the grounds of a risk assessment respecting the right of blood recipients to the protection of their health. On the impacts on simplification and/or administrative burden, EBA notes that option 1 would not allow simplification for blood establishments and the additional costs for the latter and competent authorities will be a source of inequality.