

SoHO
Draft report priorities
Nathalie Colin-Oesterlé

Protect donors and recipients with the highest quality and safety standards:

- Harmonise the implementation of the principle of voluntary and unpaid donation, in particular in order to avoid that discrepancies between national regulations encourage citizens to donate in another country than their own for financial reasons;
- Work further towards convergence of provisions on donation frequencies between Member States, by empowering the European Commission to adopt delegated acts on this very subject;
- Promote the use of the most innovative technologies to reduce the risk of human error and improve the quality of SoHO;
- Strengthen the respect of the principles of impartiality, independence and transparency in supervisory activities to protect competent authorities from undue interference and influence;
- Create a legislative framework to enhance coordination between the Commission's services, EU agencies and competent authorities regarding serious adverse events, in order to prepare for, prevent and respond to the emergence of transmissible diseases through SoHO.

Harmonise national systems to ease cross-border exchanges:

- Use more systematically the EU Coordination Committee and the EU SoHO platform established in this Regulation to optimise the exchange of information between national and European authorities;
- Limit the risk that the same SoHO depending on different legislative frameworks in different Member States arises, by giving Member States greater incentives to respect the opinions of the Coordination Committee and by strengthening cooperation with equivalent advisory bodies established by other relevant EU legislation, such as the European Medicines Agency (EMA) or the Medical Device Coordination Group (MDCG);
- Ensure that a Member State that has decided to apply stricter measures regularly reassesses its position and does not use these measures to restrict intra-EU SoHO exchanges.

Build European self-sufficiency in SoHO supply:

- Put in place a strategy for the promotion of European autonomy that defines ambitious collection targets and assesses the means to achieve them (communication, setting up a European day dedicated to essential SoHO donations, better management of available SoHO stocks, etc.);
- Develop the practice of patient blood management in order to optimise the use of SoHO while promoting less invasive therapeutic alternatives for patients;
- Give priority to therapeutic uses of SoHO in national SoHO emergency plans in the event of supply tensions within the EU.

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