Blood Transfusion Association

PROPOSAL FOR A SoHO REGULATION

Ensuring a safe and sustainable supply of blood and its components

Introduction

The **Blood Transfusion Association (BTA)** is an international non-profit trade association committed to promoting the correct use and safe supply of blood for transfusion. Through its direct membership and stakeholder network, the BTA aims to make the voice of the blood sector heard in a collaborative approach.

The BTA's objective is to ensure that the SoHO Regulation addresses the needs of patients, workers and donors. The SoHO Regulation should provide a solid foundation to counter emerging threats to supply continuity and facilitate a strong and resilient blood supply in Europe.

The BTA supports the proposal's flexible and safety-focused regulatory framework that enables the timely implementation of improved blood component products and processes for the benefit of patients and donors.

However, there are six areas the BTA would like to improve throughout the proposal:

- **Donor and patient safety**
- **Innovation**
- **Harmonisation**
- **Climate change and pandemic preparedness**
- **Stakeholder involvement and transparency**
- **Health, protection and safety of workers**

1- Donor and patient safety

The main aspect of ensuring a robust and flexible framework for blood supply is positioning patients' health as its focus. In this sense, the provisions in the legislative proposal must ensure patients have access to high-quality products while limiting adverse effects.

1.1 Recommendation

Recital 13, of the proposal, considers the donations of oocytes, bone marrow, peripheral blood stem cells and plasma a significant risk. In this regard, the SoHO sector is already strictly regulated by several EU, national and international laws. The industry and blood establishments fully comply with these provisions and take additional safety measures to minimise risks for donors and patients. The BTA contemplates that **using the term "significant" risk is unnecessary and may adversely affect donor and patient trust, as well as a sufficient blood supply.**

2- Innovation

Patients, as well as donors and healthcare workers, are all beneficiaries of innovation. The flexibility in this proposal must be preserved because it will allow a rapid adoption of innovation in the future. Devices that reduce the handling of blood bags, improve data traceability and reduce human error mean safer blood, which means that patients, workers, and even donors are protected. Recent scientific developments in the blood sector demonstrate that the new technology does not only improve patient outcomes but also contributes to the reduction of donor demand.

2.1 Recommendation

Facilitating innovation requires legal clarity and good interplay with other legislative frameworks, particularly those regulating medicinal products and medical devices. It is important to ensure that innovations, such as new medical devices or blood components can be implemented into the systems in a timely manner. The BTA believes the proposal provides an opportunity to ensure a functional and smooth validation process of medical devices. Therefore, **it is crucial to ensure that the future SoHO Regulation represents and reflects the current state of technological progress.**

The BTA supports the EC's proposal which considers the implementation and optimisation of the preferred use of processes and technologies in the Regulation's text instead of solely relying on the ECDC and EDQM guidelines. Regulations carry more weight in enforcement as they are legally binding, providing a stronger framework for adherence compared to guidelines, which are often advisory and open to interpretation. By including processing technologies in both the Regulation text and guidelines, a standardized and coordinated response can be ensured across Member States, enhancing patient safety and protecting healthcare workers. **Incorporating processing technologies in the Regulation can help address challenges related to climate change, pandemic preparedness, and promoting equality in blood donations, safeguarding the blood supply and protecting public health.** Consideration of processing technologies might not only strengthen the European supply of blood but also allow for a proactive approach to blood-safety threats and risks. All in all, this would ensure that the collected blood and blood components can be safely distributed to the European Member States.

3- Harmonisation

While blood bag sets are considered medical devices, falling within the scope of the EU Medical Devices legislation, their use for the collection of blood and blood components is regulated by the SoHO legislation. Considering that there are differences in the way EU Member States validate medical devices. **The SoHO proposal provides a unique opportunity to reduce differences in the way EU Member States validate medical devices, harmonising how validation is done.** This would additionally ensure more scientific and political collaboration on the EU level and internationally.

This can be achieved by addressing the issue of validation harmonisation during the expert and stakeholders meetings to understand what has been done in each Member State already and what could be the potential best practices. This inclusive approach helps to ensure that the validation process for blood bag set manufacturers is transparent, comprehensive, and effective in meeting the needs of patients and healthcare providers throughout the EU. This would provide clarity to blood establishments and healthcare providers, ultimately facilitating achieving equal and uninhibited patient access in Europe and greatly reducing the burden on manufacturers.

3.1 Recommendation

The BTA encourages the acknowledgement that medical device validation should be made more functional and harmonised across the EU for the blood bag set manufacturers to help ensure a safe and sufficient blood supply. This is particularly essential given the difficult regulatory environment in which blood bag set manufacturers must operate in the EU.

Throughout the EU SoHO Platform that the proposal puts in place, the authorisation of new SoHO preparation information and the evidence used for such authorisations should be shared to ensure a harmonised approach. All in all, harmonising the validation of blood bag sets across the EU is essential for ensuring patient safety, facilitating cross-border blood supply, promoting innovation and competition, and enhancing efficiency and effectiveness in blood collection and transfusion.

4- Climate change and pandemic preparedness

Current changes in Europe, such as population ageing, climate change, and more recently, the COVID-19 pandemic, have directly impacted the blood supply. The pandemic resulted in a decrease in blood donations due to lockdowns or deferrals. Whereas, climate change contributes to the rise and increased frequency of emerging pathogens.

Through proper safety and quality mechanisms, the proportion of blood from donations could be increased which would otherwise be discarded due to increased risk. This can be achieved by implementing proper quality storage mechanisms and safeguarding state-of-the-art technologies that ensure the safety of donated blood. In fact, **the Parliament has previously urged ' " Member States and the Commission to respond adequately to the new threats posed by climate change, such as the increased presence of emerging viruses and undetected pathogens, and therefore implement new existing pathogen reduction technologies that reduce known and undetected viruses and other pathogens transmitted by blood;"**[1] . Hence, blood and blood component storage becomes a critical parameter to optimise blood supply, especially in the context of pandemic preparedness.

4.1 Recommendation

Consequently, **the BTA proposes that national SoHO emergency plans are as detailed as possible including an analysis of potential supply gaps and a clear strategy for communication** between authorities but also to citizens. The BTA esteems it is important to add these requirements to the SoHO Regulation proposal because in the event of an emergency or disaster, the supply of substances of human origin, may be disrupted or compromised. By having national SoHO emergency plans that are as detailed as possible, including an analysis of potential supply gaps and a clear strategy for communication between authorities and citizens, they would ensure that these substances are allocated effectively and that there is a coordinated response to emergency situations.

Additionally, climate change contributes to the rise and increased frequency of emerging pathogens. ECDC's epidemiological reports and vector maps tracking the prevalence of vector-borne diseases in Europe show the geographical expansion of mosquitoes responsible for the transmission of diseases such as dengue, Zika and chikungunya[2] . Only between 2009 and 2019, the confirmed cases of dengue showed a 700% increase across the EU Member States. These changes carry an increased risk of a future bloodborne pandemic in the EU. Therefore, **the BTA proposes that pandemic preparedness and climate change be highlighted to combat future new disease outbreaks and unknown pathogens.** A bloodborne pandemic could do untold damage, but steps can be taken to reduce the risk of such an event.

1 P6_TA(2008)0410 Mid-term review of the European Environment and Health Action Plan 2004-2010

2 https://www.ecdc.europa.eu/en/surgical-site-infections/surveillance-and-disease-data/all-annual-epidemiological-reports

5- Stakeholder involvement and transparency

All stakeholders should be considered to ensure that all perspectives are taken into consideration and that uniformity of applicability is established across the EU.

Opportunities for increased stakeholder collaboration are a good way to safeguard compliance with minimum standards. As well as confirming that the new legislative framework promotes a sustainable, innovative environment that fosters dynamic research, development, and innovation. Additionally, by creating multistakeholder groups the Regulation facilitates processes that ensure a sustainable, innovative environment which promotes research, development and innovation in a dynamic manner. Consequently, the proposal will ensure transparency and a safe blood supply continuity.

5.1 Recommendation

Therefore, the BTA considers it crucial to ensure consistency by providing more opportunities for stakeholder collaboration. **The industry's inclusion as an observer to the SoHO Coordination Board (SCB) established by the SoHO Regulation proposal will bring valuable expertise and perspectives to the Board's work**. As a key stakeholder in the manufacture, testing, and distribution of blood and blood components, the industry can provide technical knowledge and practical insights that may be critical to the SCB's decision-making processes.

Furthermore, since the EDQM is responsible for developing guidelines that extend beyond just the EU Member States, **it is important to include transparency measures such as stakeholder consultations in the SoHO Regulation proposal to ensure transparency and the active participation of EU stakeholders**. Relying solely on EDQM guidelines as the primary source for certain provisions in the proposed SoHO Regulation could pose a significant risk as the guidelines are developed for use in Europe and may not align with the regulatory frameworks and safety standards of other regions. While EDQM guidelines are widely respected, they do not have the force of law in the EU, and Member States may choose to adopt their own regulations or guidelines from other organizations. This diversity could pose challenges in achieving consensus and relevance across all member states, potentially leading to guidelines that are not aligned with EU standards and risking negative consequences for the health and safety of EU citizens.

6- Health, protection and safety of workers

Directive 2000/54/EC[3] regarding biological agents at work specifically states that "the risk of exposure must be reduced to as low a level as necessary in order to protect adequately the health and safety of the workers concerned". The proposal for a SoHO Regulation should be consistent with this Directive to ensure that the collected blood and blood components can be safely distributed to the European Member States.

6.1 Recommendation

The safety of personnel handling SoHOs should be also prioritised in the legislative text as they are exposed to certain risks by handling SoHOs.

It is equally crucial to guarantee the safety and well-being of donors and patients as well as personnel who handle SoHOs. These workers may be exposed to infectious diseases or other hazardous substances, and appropriate safety precautions must be implemented to safeguard their health.

3 EUR-Lex - 32020L0739 - EN - EUR-Lex (europa.eu)