international plasma and fractionation association

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IPFA general position on European Commission proposal for new SoHO regulation

The International Plasma and Fractionation Association (IPFA), the association representing the not-for-profit plasma fractionation and plasma collection sector, welcomes the European Commission proposal for a new regulation on SoHOs. IPFA is particularly pleased to see that many of its recommendations have been considered in this proposal. IPFA also recognises the intense preparative work accomplished by the Commission in integrating all SoHOs in the proposal.

Particularly IPFA welcomes:

- the integration of **plasma for fractionation** in the definitions and obligations of SoHOs for donation, collection, and testing, allowing it to be recognised as part of the human body and not as a commodity.
- the articles dedicated to **donor protection**, both by means of surveillance requirements using common standards before, during and after donation and by means of regulating donor incentives. IPFA applauds the preservation of the current principle of voluntary and unpaid donation (VUD) in line with Article 3 of the EU Charter of Fundamental Rights that prohibits the commercialisation of the human body and the **principle of 'financial neutrality'**
- the introduction of a **mandatory threshold of compensation** that need to be set by MS
    - however, the EC could define a framework for setting the threshold e.g., based on the MS GDP or mean/minimal salary.
    - also, IPFA would like to know if the Commission Regulation can **include a diversity of incentives**, without limiting itself to financial compensation which presents limits and risks, by proposing initiatives also in the field of health, solidarity, culture, education, possibility of accessing health care in the context of prevention, etc.
- that Repeated donation of plasma is considered to "imply a significant risk", especially when frequent. Such a definition could be defined in the EDQM blood Guide when addressing plasma for fractionation. Also, IPFA suggests the EC to request for **formal studies on frequent plasma donations** to be coordinated by the SoHO platform based on raw data submitted to the platform
- the setting of most-up-to-date guidelines and rules system **to incorporate innovation and adaptation to societal changes.** This clearly defined setting by the EDQM (Blood Guide and guidelines), as well as by the ECDC, brings reinsurance that there will be harmonised and monitored guidelines and rules, and that there is a network to ensure their implementation
- the aim for a stronger relationship between related Legislation frameworks (ref. e.g. PMDPs and Medical devices)

- the new SoHO coordination board (SCB) and SoHO platform, and the clear will of the Commission for **better transparency in all processes**, including guidelines drafting. IPFA also understands that **experts from the operational sector could be invited in these processes**, and applauds this initiative
- the implementation of national SoHO authorities, as a mean to improve the Quality management of SoHO Entities throughout the EU
- obligations of competent authorities, training of MS inspectors, harmonisation of practices among MS and controls of MS SoHO national authorities' activities
- IPFA is pleased with this requirement **that competent authorities that act in the public interest, are appropriately resourced and equipped**
- the organisation of **monitoring Supply Continuity** throughout the EU. IPFA appreciates the implication of the MSs in **encouraging the public sector involvement** in the collection of Plasma for Fractionation, which also would imply supportive fundings.
  However, in particular for plasma:
    - Self-sufficiency shall not only take into account amounts collected in each MS. It should also be **related to the use of PDMPs reflecting best clinical practices.**
    - **This needs to be considered in the management of plasma amounts collected in each MS** as well as in the union, **to ensure equitable patient access to products** manufactured from this SoHO starting material.

IPFA hopes that our strong support of the proposal and our including remarks will be taken into account in the final process. IPFA will continue to work with the involved stakeholders to ensure that this proposal leads to a satisfactory and smooth implementation. A strong and clear regulation will support the goal of the EU commission and of our member organisations.

About IPFA

The International Plasma and Fractionation Association (IPFA) is an association representing organisations engaged in the collection of plasma and fractionation thereof into plasma-derived medicinal products. IPFA´s members are from the not-for-profit sector and come from all over the world. They represent both blood establishments collecting plasma and manufactures (fractionators) who produce the plasma-derived products.

IPFA´s aim is to enable robust, safe supply and patient access to life-saving plasma-derived medicines, while strengthening the contribution and ability of the public sector to collect plasma within their communities. IPFA encourages and help blood establishment to increase their collection of plasma for fractionation and their aims to conduct this task alongside the collection of other blood components, with a strong an emphasis on donations without financial gain, donor health protection and in the interest of public health.

IPFA represents its members in conversations with competent authorities, medicines agencies, regulatory agencies, political officials, patient organisations, donor associations, commercial counter parts and other interested stakeholders in the field. IPFA arranges scientific and educational events and workshops related to the field of plasma donation and fractionation.

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