

**SoHO Coordination Board (SCB)**

**Guidance on compensation criteria**

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## Objective and scope

In accordance with Article 69(1)(g) of Regulation (EU) 2024/1938<sup>1</sup> (hereinafter the “SoHO Regulation”), the SCB has the task to document the practices followed by the Member States to establish the conditions for compensation as referred to in Article 54(2). Therefore, a survey was sent to the SCB in order to map the practices of Member States regarding compensation [reference to the document reporting the survey results to be included]. This survey covered all SoHO regulated under the SoHO Regulation, but the information provided by the Member States concerned compensation practices set up under the Blood and Tissues & Cells Directives. Therefore, the SCB aims to give guidance to Member States on setting criteria for donor’s compensation in line with the SoHO Regulation that take into consideration current practices, while safeguarding the principle for voluntary unpaid donation (VUD) and financial neutrality that Member States must comply with in accordance with Article 54(2) of the SoHO Regulation. This document provides guidance and is therefore not legally binding.

The compensation of expenses such as healthcare expenses, sick leave or compensation arrangements in case of disabling or incapacitating conditions related to the donation fall outside the scope of Article 54 of the SoHO Regulation and are therefore outside of the scope of this document. Appreciation for the donor, for example by a small token (e.g. a pen, mug, tote bag) or an act of appreciation by a third party, like an employer of the donor, that gives the donor a day off from work, also falls outside the scope of Article 54 and therefore outside of the scope of this document.

## Background

According to Article 3 of the Charter of Fundamental Rights of the European Union it is prohibited to make the human body and its parts as such a source of financial gain. Moreover, the use of financial incentives for donations of substances of human origin (SoHO) can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients. Therefore, SoHO donation should be voluntary and unpaid, and be founded on the principles of altruism of the SoHO donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation contributes to the respect for human dignity and the protection of the most vulnerable persons in society.

The ‘Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors’ from the Council of Europe Committee on Bioethics (2018) specifies that while financial gain should be avoided, compensation should be able to be acceptable to prevent SoHO donors being financially disadvantaged by their donation. Therefore, compensation to remove any such risk is deemed appropriate as long as it endeavours to guarantee financial neutrality and does not result in a financial gain for the SoHO donor. Nor should it constitute an incentive that would cause a SoHO donor not to disclose relevant aspects of their medical or behavioural history or to donate in any way that could pose risks to their own health and to that of prospective recipients, in particular by donating more frequently than it is allowed.

It should be possible for compensation to consist of the reimbursement of expenses incurred in connection with SoHO donation or of making good of any losses, preferably based on quantifiable criteria, associated with the donation of SoHO. Compensation schemes shall not result in

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<sup>1</sup> Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.

competition between SoHO entities for SoHO donors, including cross-border competition and in particular between SoHO entities collecting SoHO for different purposes.

## Provisions and definitions as specified in the SoHO Regulation

Article 54 of the SoHO Regulation sets standards for voluntary and unpaid donation of SoHO.

Article 54(1) specifies that SoHO entities shall not provide financial incentives or inducements to SoHO donors or any person granting consent on their behalf. However, compensation of living SoHO donors is allowed (Article 54(2)) under the condition that:

- it is in accordance with the principle of voluntary and unpaid donation;
- it is based on transparent criteria, including through fixed allowances, or through non-financial forms of compensation;
- the conditions for such compensation shall be established in national legislation, including by setting an upper limit for compensation that shall endeavour to guarantee financial neutrality;
- the setting of conditions for such compensation shall be based on criteria that take into account the practices documented by the SCB, as referred to in Article 69(1), point (g);
- SoHO donors may choose not to be compensated.

In addition, when Member States allow for the compensation of SoHO donors as referred to Article 54(2) of the SoHO Regulation, the conditions for such compensation applied by each Member State shall be made available to the SCB for sharing with the SoHO national authorities of the other Member States via the EU SoHO Platform and the information shall be updated without undue delay if it has been modified (Article 54(3)).

### **Definitions according to the SoHO regulation:**

**Compensation** means making good of any losses or the reimbursement of expenses associated with SoHO donation (Article 3(56)).

**Financial neutrality of donation** means that no financial gain or loss will be incurred by the SoHO donor as a result of the donation (Article 3(57)).

## Suggested criteria regarding compensation

**Basic principle: Endeavour to guarantee financial neutrality of donation:** while on one hand financial gain when donating SoHO cannot be incurred, financial losses or disadvantages should be avoided.

To achieve the basic principle as outlined above, Member States may consider applying the following **criteria** when setting conditions for compensation which can within a MS differ per SoHO-type, if appropriate:

- Cover only **expenses** and **loss of earnings**:
  - In case of expenses: Member States may choose to provide a fixed amount to simplify administration or to cover the actual expenses. In the latter case, the donor has to prove that expenses were made (e.g. by providing receipts). An upper limit shall be

set that is proportionate and in-line with the basic principle outlined above. For example, a Member States could decide to reimburse the actual travel cost up to 50 km for blood donation in case blood donation centres are always within 50 km reach of citizens in that Member State. Furthermore, Member States can decide to use an upper limit to prevent non-proportionate and unwanted costs, for example the compensation of a flight ticket.

- In case of loss of earnings: Member States may choose to provide a fixed amount to simplify administration or to cover the actual loss of earnings for specific SoHO such as those for which it is necessary to visit the donation centre (e.g. for preparatory treatments, collection or follow-up) and the visit and/or time of recovery is estimated to be long. For these circumstances the donor has to provide evidence for the loss of earnings. Member States can decide to set an upper limit that is proportionate and in-line with the basic principle outlined above.
- In case of a fixed rate scheme, the scheme also need to be in accordance with the principle of financial neutrality. This can be achieved by e.g. using the median travel expense of donors. With this type of compensation, it is accepted that for some donors the compensation will be lower than the actual cost/loss while for others higher. However, in case of large differences between the actual cost/loss and the amount of compensation paid, a fixed rate scheme may not be the appropriate tool as it may not guarantee financial neutrality.
- **The amount of the compensation** should be proportionate to the local gross domestic product (GDP) per capita, which should be considered to determine the upper limit for compensation.
- **The following expenses could be considered for compensation, when relevant, appropriate and proportionate:** e.g. travel expenses to the SoHO entity, parking expenses, hotel expenses, meal expenses.
- **In case non-financial compensation is used** (e.g. parking voucher or meal voucher), this should mirror the value that follows the set criteria.
- Considering that compensation is provided to achieve financial neutrality of donation, and in order to secure safety of the SoHO and its recipient by avoiding that there is a driver to give misleading and erroneous information during the donor selection, no distinction in compensation should be made when **collection is eventually not possible or unsuccessful**. However, the compensation should cover only the activities to which the donor took part. Of course, in case a donor travels to a donation side on false pretences, SoHO entities are entitled to refuse any kind of compensation.
- Compensation schemes shall **not result in competition** between SoHO entities for SoHO donors, including cross-border competition and in particular between SoHO entities collecting SoHO for different purposes.
- **In case of cross-border competition** between SoHO entities for SoHO donors, Member States may consider to monitor this and taking preventive measures, for example by establishing bilateral or multilateral agreements. Preventive measures that could be considered are e.g. to allow only donors that reside in the Member State where donation takes place or to request entities and establishments located in a specific geographic area to adapt the amount of compensation in case of cross-border donors to the compensation scheme, including no compensation, used in the neighbouring Member States.
- If the donor requires the **justified assistance of a third party**, the accompanying person may also be entitled to the same compensation as the donor.

- **A request for compensation, or part of the compensation, can be refused** by a SoHO entity in case the expenses made by the donor, or a third party in case of justified assistance of a donor, are already compensated in another way.