

## "Non-remunerated donation": a tautology?

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### The ban on deriving profit from the human body or its parts

Both blood and the act of giving are part of what makes us human; blood is vital for our bodies and giving is one of the noblest gestures we can make. Both have been analysed, described and studied in the arts, by philosophers, and in numerous forms of cultural enquiry throughout the centuries<sup>1,2</sup>. The ban on trade in the human body or its parts or on deriving profit from such activity has been recognised and promoted by eminent institutions, and generic principles concerning these issues are applied to blood, cells, tissues and organs. In particular, voluntary, non-remunerated donation is recognised by all the major competent bodies in the field as the foundation for the safe and sustainable supply of blood and blood products. For example:

- 1) the Melbourne Declaration of the World Health Organization (WHO) states that "evidence supports that regular voluntary non-remunerated blood donors are the cornerstone of a safe and sustainable national supply of blood and blood products sufficient to meet the transfusion requirements of the patient population"<sup>3</sup>. The WHO Declaration of Rome, drawn up by 53 experts representing health ministries, national blood programmes, public health agencies and other organisations, calls on the relevant national authorities to "introduce legislation to prohibit payment in cash or in kind for the donation of blood, plasma and other blood components"<sup>4</sup>.
- 2) The European Union Directive 2002/98 states that "Voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health"<sup>5</sup>. Article 3 of the EU Charter of Fundamental Rights includes a "prohibition on making the human body and its parts as such a source of financial gain"<sup>6</sup>.
- 3) The Council of Europe Recommendation R(95)14 states that "The donation of blood, plasma, or cellular components should comply with the ethical principle of voluntary, non-remunerated donation applicable to all removal, grafting and transplantation of human substances"<sup>7</sup>.

The non-remuneration of blood donations is based primarily on ethical principles, but it is also supported by other considerations, three of which are of particular importance:

- 1) patient safety: a correlation has been found between blood and plasma-derived products collected from paid donors and an increased risk of transmitting infectious diseases<sup>8</sup>;
- 2) continuity in supply and self-sufficiency in systems: there is an evident risk that the existence of organisations that collect blood from paid donors alongside health services collecting from voluntary non-remunerated donors will lead to competition<sup>9</sup>;
- 3) donor safety: donors who are paid to give blood may be tempted to do so too frequently, thereby placing their own health at risk<sup>10</sup>.

### Why is it specified that a donation must be non-remunerated?

To those familiar with the complex organisational systems for the donation of blood, cells, tissues and organs, the expression "non-remunerated donation" that appears frequently in specialised documents and texts may seem a tautology, while the expression "paid donation", which is also used, is an obvious paradox. How can a "donation" be "remunerated"? A donation is defined as "something given, presented, or donated as a gift"<sup>11</sup>. Any remuneration, therefore, mocks the notion of "donation"; it is not a donation if it has been paid for.

The professionals in the field know that there are clear reasons for using this expression. These are related to healthcare organisation and policy considerations; even in systems in which donations are strictly non-remunerated, economic factors are necessarily present.

Firstly, it is clear that donors should not incur any expenses directly associated with a donation (such as, and in particular, travel costs) or lose earnings (through absence from the workplace). The "Code of Ethics for Blood Donation and Transfusion" published by the International Society of Blood Transfusion states that: "A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non/remunerated donation"<sup>12</sup>.

Secondly, the preservation and, sometimes, the processing of human body material are associated with

movements of money, given that the institutions that use the material reimburse those that process and preserve it. For example, the "WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation" (in particular, the Commentary to Guiding Principle 5) state that the "need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted"<sup>13</sup>.

Against this complex background, notions such as a "ban on trading" or a "ban on deriving profit" from the human body, which might seem self-evident, have to be interpreted. This is not always a straightforward task, as evidenced by the complications involved in interpreting Article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which states that "The human body and its parts shall not, as such, give rise to financial gain"<sup>14</sup>.

The present article does not presume to suggest additional arguments to those already proposed and amply discussed in the literature over decades. Instead, it offers some tentative considerations concerning the issue of "non-remunerated donations" as seen from the point of view of a bioethicist.

## The view of a bioethicist

### Donation

- 1) The premise is unquestionable: the human body and its parts should never, in any circumstances, give rise to profit. On this point there is complete agreement among the most authoritative international institutions, and it necessarily follows that the donation of blood (cells, tissues or organs) should be voluntary and not linked to any form of payment.
- 2) The notion of "non-remuneration" does not rule out the possibility of offering legitimate "reimbursements" to donors, provided that a clear line can be drawn between legitimate forms of reimbursement (for expenses incurred or for time off work) and other forms of benefits (not only financial) associated with a donation. Any reimbursements should be strictly limited to actual costs sustained or missed earnings directly linked to the donation.
- 3) The possibility of compensation for any harm attributable directly to the donation should not be excluded.
- 4) No form whatever of "inconveniences" associated with a donation should be allowed. The notion of "inconvenience" could be used to disguise the recruiting of "voluntary" donors in times of a shortfall in supply and, consequently, the exploitation of vulnerable groups.
- 5) The promise to donors of preferential rates for healthcare not linked to the donation is not admissible.

- 6) Any "rewards" should not be allowed to conceal forms of payment; such rewards should, therefore, have no monetary value and should not be transferable to third parties.

### Products derived from donated human biological material

- 1) Blood and other materials of human origin (such as parts of bones removed during surgery) can be used to derive products with a commercial value. Even though the donor is no longer identifiable, the material is still the fruit of an act of unsolicited generosity and should, therefore, be used only for therapeutic purposes or for biomedical research. This means that its "for profit" use by the cosmetics industry should not be allowed.
- 2) In the event that the use of this material for therapeutic purposes or for biomedical research should generate any form of profit, such profit should be assigned to the institution concerned.

### General rules

- 1) Consent to a donation should be given in complete autonomy and in full compliance with current legislation.
- 2) It is the responsibility of legislators and national authorities to ensure that donations are not linked to any form of economic benefit. They should also promote awareness of the issues associated with donations and of the life-saving potential of a simple gesture of altruism.
- 3) Some states that are signatories to declarations that assert the principle of the non-remunerated nature of donations, such as those listed above, nonetheless allow forms or reimbursement that can, more or less explicitly, be construed as actual payments. In such cases, for the sake of consistency, the expression "donation" should not be used: if it is "remunerated" it is not a donation.

### Disclosure of conflicts of interest

*CP is a member of the "Ad hoc working group on the prohibition of making a financial gain from the human body" of the Council of Europe.*

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