



## EBA Fact sheet on Voluntary Non-Remunerated Donors

### Context

Directive 2002/98/EC<sup>1</sup> states that “Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations”. When defining “voluntary and unpaid donation”, Directive 2002/98/EC endorses the Council of Europe widely acknowledged definition of “voluntary non-remunerated donation”<sup>2</sup>:

*Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or 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.*

According to the European Commission 2016 implementation report on these measures<sup>3</sup>, “in all MS, donors are given some form of compensation/incentive”, but there are “divergent understandings what practices of giving compensation/incentives to donors comply with the principle of “unpaid” donation”.

This framing of measures of encouragement toward donors as “compensation” can be problematic, as “compensation” is a concept that was not envisaged in the definition in the definition of voluntary non-remunerated donation from the Council of Europe. The compliance of “compensation” with this definition is still debated. This was illustrated in 2010 by a judgement of the European Court of Justice<sup>4</sup>.

Voluntary non-remunerated donations (VNRD) have proven to secure a safe and sustainable blood supply in Europe. The EU should take measures to maintain and further develop this donation culture based on European values.

### Unclear definitions

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<sup>1</sup> Directive 2002/98/EC, 2003

<sup>2</sup> Council of Europe, Committee of Ministers, Recommendation No. R (95) 14 of the Committee of Ministers to Member States on the protection of health of donors and recipients in the area of blood transfusion, 1995

<sup>3</sup> Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, 21 April 2016, [European Commission](#).

<sup>4</sup> Judgement of the Court (First Chamber) in Case C-421/09, 9 December 2010



What is covered by donor compensation is at the heart of the debate on the delineation between voluntary non-remunerated and remunerated donations. Other widely acknowledged definitions are also useful to bear in mind; the definitions provided by the Nuffield Council on Bioethics in a 2011 report (*see annex*)<sup>5</sup> are especially useful in that regard.

It should also be recalled that compensation is neither an obligation nor a prerequisite, and that donations can also be non-compensated, for example when the donors only receive simple drinks and food, the provision of which derives from a medical obligation.

#### **Impact on blood safety**

Scientific research has shown remunerated blood donors to have a higher risk of blood-borne infectious diseases than voluntary non remunerated donors<sup>6</sup>. As no viral inactivation method is yet applicable to all types of components, collecting blood components from voluntary non-remunerated donors is a key safety measure (complementary to donor screening).

By contrast, for plasma-derived medicinal products (PDMP), the safety gain from collecting plasma from voluntary non-remunerated blood donors has been considered of relatively less importance, given the large number of complementary measures, including several steps of viral inactivation, which are implemented during the production process.

#### **Impact on blood availability**

The increased risk of infectious disease from remunerated donors has never been outweighed by a demonstrated need to pay donors to ensure the availability of blood components for transfusion.

The situation is different for plasma for fractionation (Pff) and PDMP, for which most stakeholders recognize that currently it would not be possible to meet the patients' growing needs without plasma from remunerated donors. The EU is not self-sufficient in Pff and PDMP, and steadily increasing demand requires significant import flows of Pff and PDMP from third countries into the EU, mostly coming from remunerated/compensated donors<sup>7</sup>. This supply situation could however be jeopardised<sup>8</sup>.

Independent of such a threat, all parties (blood establishments, industry, patient associations, donors associations) agree on the need for both recovered and source plasma and on the need to avoid wastage of recovered plasma, as described in the Dublin Consensus Statement on optimised supply of PDMP<sup>9</sup>.

#### **Ethical acceptability for donors**

To protect donors' and patients' safety, transactions of human bodily materials should comply with the well acknowledged four principles of biomedical ethics: autonomy, non-maleficence,

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<sup>5</sup> Nuffield Council on Bioethics. Human bodies: donation for medicine and research. 2011.

<sup>6</sup> Van der Poel CL et al, *Vox Sang*, 2002; 83: 285–293.

<sup>7</sup> Creativ Ceutical Report, revised by the Commission to include stakeholders' comments. An EU-wide overview of the market of blood, blood components and plasma derivatives focusing on their availability for patients, 2014.

<sup>8</sup> See the *EBA fact sheet on European self-sufficiency for blood components and plasma for fractionation*

<sup>9</sup> O'Mahony B et al. *Vox Sang*. 2010; 98: 447-50.



beneficence and justice<sup>5,10,11</sup>. Protection of donor's dignity, involving the prohibition of making the human body and its parts as such a source of financial gain, has been strongly encouraged by the Council of Europe Oviedo Convention<sup>12</sup>.

The concept of voluntary non-remunerated donation puts into practice these ethical principles in the field of blood and plasma donation. There are however wide variations between EU Member States, and a lack of common practical tools, in the identification of practices toward donors which are compatible with voluntary non-remunerated donation.

The Nuffield Council on Bioethics<sup>5</sup> intervention ladder (*see annex*), based on clearer definitions and ethical principles, is in this regard a useful tool for considering the ethical acceptability of different forms of encouragement to donors.

This approach, which is increasingly accepted by the plasma industry as well<sup>13</sup>, would help to further develop VNRD as the best way to ensure both a safe and sustainable blood and blood component supply, including for plasma for fractionation, in order to meet the patients' needs and a safe and sustainable donor population.

#### ***Issues identified which could be solved in revised Directives***

- In the current Directive, VNRD is “encouraged”, but it is not compulsory.
- While collection of plasma for fractionation in Europe has increased substantially in the last decade, the share of plasma collected from voluntary non-remunerated donors has decreased, and the share of paid donations has increased.
- Payments to blood and plasma donors erodes the current community-based, non-remunerated, donor population, which is the key element to secure a sustainable blood supply. In countries with dual systems (where unpaid and paid collection coexist), blood establishments who collect components for transfusion encounter increasing difficulties in recruiting and retaining unpaid donors.
- While the general framing of measures toward donors as “compensation” can be helpful, its compliance with the definition of voluntary non-remunerated donation from the Council of Europe is debated.
- This uncertainty of definitions allows for substantial differences in interpretation of the practices toward donors which are compatible with voluntary non-remunerated donation.
- This in turn undermines the objective of “ensuring that blood and blood components are in so far as possible provided from such donations” set in Directive 2002/98/EC. In fact, in the last

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<sup>10</sup> Beauchamp TL, Childress JF: Principles Biomedical Ethics, 5th edn. New York, Oxford University Press, 2001, ISBN 0-19-514332-9.

<sup>11</sup> Folléa G et al. Blood Transfus 2014; 12(Suppl 1):s387–s388.

<sup>12</sup> European Convention on Human Rights and Biomedicine, 1997 (“Oviedo Convention”).

<sup>13</sup> European Medicines Agency, Guideline on plasma-derived medicinal products, 2011; EMA/CHMP/BWP/706271/2010.



five years there has been very limited progress in ensuring an increase in the share of blood and blood components coming from voluntary non-remunerated donors.

**EBA view on the way forward**

- Both for blood safety and ethical reasons, all labile blood components should come from voluntary non-remunerated donors
- Both on ethical grounds and in order to limit the risk of paid plasma collection eroding the voluntary non-remunerated donor base, which is essential to the supply of blood components for transfusion, European legislation should set a long-term goal that, in a timeframe to be defined, all plasma donations for fractionation should also come from VNRD.
- This objective can be achieved through better definition of the acceptable levels of compensation which are compatible with the definition of voluntary and unpaid donation, and implementation of these definitions under close Member States scrutiny.

***EBA recommendations on VNRD in future European Directives***

1. Strengthen the implementation of the necessary measures to encourage voluntary and unpaid blood donations by the Member States, in line with article 20, paragraph 1, of Directive 2002/98/CE
2. Better define “compensation” for donors of blood, blood components and plasma, eg. through the adoption of the Nuffield Council on Bioethics definition (*a recompense of donors for non-financial losses, e.g. inconvenience, time*), as a complement to the classical definition of voluntary non-remunerated donation.
3. Encourage the development and use of tools, such as the intervention ladder of the Nuffield Council on Bioethics, which can help in identifying non-altruist-focused forms of compensation for blood, blood component and plasma donors (which are ethically questionable), and altruist-focused forms of encouragement (which are ethically acceptable and compatible with the Council of Europe definition of VNRD).
4. Promote the replacement of non-altruist-focused forms of compensation by altruist-focused forms of compensation for blood, blood component and plasma donors.
5. Introduce in European legislation a binding objective of achieving 100% supply of labile blood components from voluntary non-remunerated donors<sup>14</sup>.

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<sup>14</sup> Proposed wording: *All labile blood components for transfusion shall come from voluntary non-remunerated donors. Member States shall take the necessary measures to ensure that all blood components for transfusion are provided from voluntary and unpaid blood donations.*



Annex

***The Nuffield Council on Bioethics report***

**“Human bodies: donation for medicine and research”, 2011**

In the 2011 report *Human bodies: donation for medicine and research*, the Nuffield Council in Bioethics, a leading institution in the United Kingdom, introduces concepts and definitions which are helpful in further advancing the implementation of voluntary non-remunerated donation of blood products, through better and more harmonized understanding of practices that are compatible with VNRD.

**The intervention ladder**

The report outlines that interventions to promote donation can be understood and classified according to a continuum, or ladder. Up until a certain point (or “rung”), the interventions are “altruist-focused” (rung 1-4), while rung 5 and 6 comprise interventions which are non-altruist focused.

**Rung 1: information** about the need for the donation of bodily material for others’ treatment or for medical research;

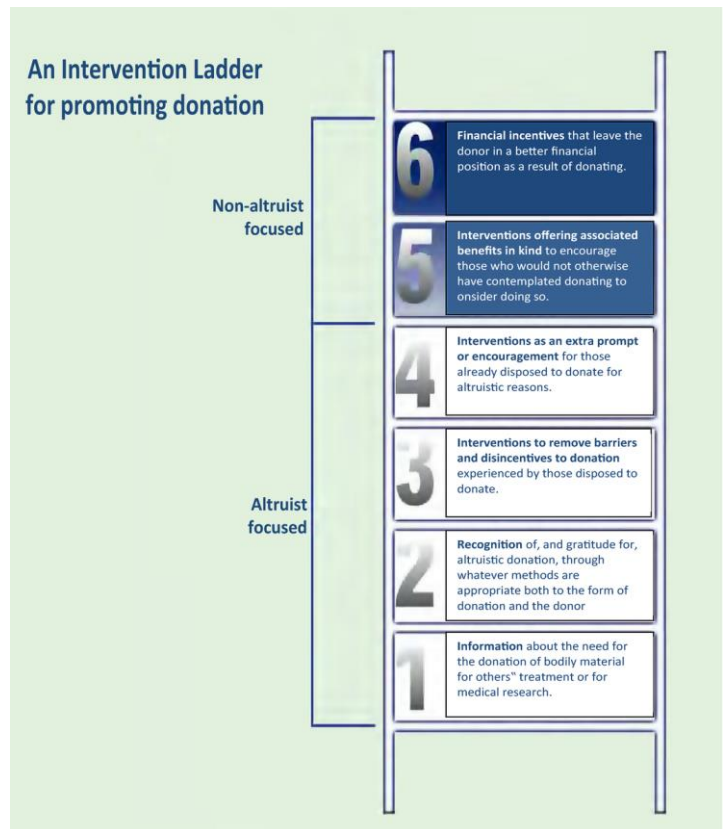
**Rung 2: recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned;

**Rung 3: interventions to remove barriers and disincentives to donation** experienced by those disposed to donate;

**Rung 4: interventions as an extra prompt or encouragement** for those already disposed to donate for altruistic reasons;

**Rung 5: interventions offering associated benefits in kind** to encourage those who would not otherwise have contemplated donating to consider doing so; and

**Rung 6: financial incentives** that leave the donor in a better financial position as a result of donating.



A comparison of each of the six “rungs” of this ladder with the definition of VNRD of the CoE has shown that rungs 1-4, classified as altruist-focused (ethically acceptable), are fully compatible with



the definition of VNRD of the CoE, while rungs 5-6, classified as non-altruist-focused (ethically questionable), clearly do not comply with the CoE definition of VNRD<sup>15</sup>. Further analysis has shown that the Nuffield Council on Bioethics intervention ladder could help in identifying non-altruist-focused forms of compensation of blood and blood components donors and to replace them by altruist-focused forms of compensation<sup>15</sup>.

#### Definitions

The report also outlines definitions regarding the different forms of payments made in connection with bodily material, which are helpful in providing a clearer definition of “compensation”.

**Payment:** a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases;

**Recompense:** payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the **reimbursement** of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or **compensation** for non-financial losses (such as inconvenience, discomfort and time).

**Reward:** material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes **remuneration**.

**Purchase:** payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg).

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<sup>15</sup> Folléa G. Donor compensation and remuneration – is there really a difference? ISBT Science Series 2016,11 (Suppl. 1), 3–9.