

Evaluation of EU legislation on blood: a bioethical point of view

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Abstract: A review of the European Union (EU) regulations concerning blood, tissues, and cells of human origin is under way in the EU. From the ethical point of view, the non-remuneration of donations and the ban on deriving gain from human biological materials are of particular significance. While the basic ethical principles involved in the procurement, preservation, and use of these materials are the same, their practical application should be adapted to the specific context of each material. In the case of donation and use of blood, in particular, the issue of legitimate reimbursements to donors and for transfusion centers has to be managed in accordance with the principle of non-commercialization. There is also a need for strict rules to avoid possible commercial spillover effects from blood-derived products. The author proposes ethical criteria regarding reimbursements to donors, costs associated with processing, and the development (and possible marketing) of products.

Keywords: bioethics, blood, legislation, Europe, transfusion

Introduction

The European Commission has begun the process of evaluating European Union (EU) legislation¹ concerning blood, tissues, and cells of human origin, in particular Directives 2002/98/EC² and 2004/23/EC,³ together with the subsequent implementing technical directives (Directives 2004/33/EC⁴ as amended, 2005/61/EC,⁵ 2005/62/EC,⁶ 2006/17/EC⁷ as amended, 2006/86/EC⁸ as amended, and Directive (EU) 2015/566⁹).

This paper offers a few comments concerning some of the ethical aspects of Directive 2002/98/EC on human blood and blood components.

Preliminary remarks

Two basic assumptions seem opportune:

1. According to the roadmap proposed by the EU, “aspects which fall within the competence of Member States, such as clinical application and ethical decisions, are not covered by this evaluation.”¹ However, the scientific and technical aspects cannot be treated separately from those of an ethical nature, and the ethical importance of the requisites set down in Directive 2002/98/EC cannot be ignored. The following are some of the requisites with clear ethical implications:

- the need for adequate measures to encourage voluntary unpaid blood donations;
- the requirement that prospective blood donors be given appropriate information, such as the details of the procedure involved and the opportunity to change their

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minds, as well as the need to provide personal data, such as their medical histories;

- the need for blood to be collected and tested only by designated authorized, accredited or licensed establishments with suitably qualified personnel;
 - the need for establishments to have quality systems in place;
 - the need for blood and blood components to be traceable from donor to recipient and vice versa and for the data to be kept for at least 30 years;
 - the requirement that any serious adverse events arising from accidents or errors be notified to the competent authority;
 - the requirement that the data collected, including genetic information, be rendered anonymous so that the donor cannot be identified;
 - the need for blood establishments to evaluate all blood donors, test each donation and ensure proper storage, transportation, and distribution of the donated blood.
2. The EU is also in the process of updating Directives on biomedical matters issued between the end of the last century and the beginning of this century. Clinical trials, for instance, are now covered by Regulation 536/2014¹⁰ and medical devices by Regulations 745/2017¹¹ and 746/2017,¹² all of which amend and replace the earlier Directives. This itself is significant, since Regulations, unlike Directives, are immediately applicable in individual states, thus removing the flexibility previously allowed to member states in regard to the transposing of Directives.

General considerations

A comprehensive assessment of EU legislation on blood, tissues, and cells¹ of human origin involves a multitude of questions. The roadmap for this evaluation process groups the issues into the following categories: relevance, effectiveness, efficiency, coherence, added value.

The following examples of ethical issues involved in the different categories are by no means exhaustive:

Relevance

- The solidity of the entire regulatory framework requires that all the rules on blood, cells, and tissues be based on the same ethical values and principles. The implementation of these values and principles will then have to be applied to specific circumstances and adapted in accordance with the type of biological material involved. In particular, because blood can be donated repeatedly, there

are peculiar aspects of blood donation that do not apply with other types of human biological material. In adapting rules to specific cases, however, no concessions should be allowed where common principles are at stake.

Effectiveness

- The question of safety for donors (as well, obviously, as for recipients) deserves special attention.
- The emergence of new infectious diseases could make additional tests necessary for donors.
- The introduction of modern marketing techniques to attract and retain donors and the creation of sophisticated donor databases, to ensure that a sufficient number of donors enter into relationships with their blood establishments, should not be allowed to become a form of pressure that induces feelings of guilt in individuals who do not wish to donate or who cease donating. Another aspect requiring attention is the costs and sources of financing for such marketing techniques, as well as what form they should take.

Efficiency

- Demographic changes such as the increasing age of populations and the fall in births, as well as the impact of migration, will lead to changes in both the supply of and the demand for blood, which must be borne in mind.

Coherence

- The Directive focuses mainly on the product, though it might be appropriate to focus more on patients and donors, while also bearing in mind the development of the “Patient Blood Management” approach.
- In the interests of consistency with other legislation, it would be useful to encourage greater clarity regarding the classification and regulation of biological products obtained from human blood, particularly blood components not for use in transfusions.
- The regulations regarding blood, tissues, and cells should be in line with those applying to trials of Advanced Therapy Medicinal Products (ATMPs).
- There are some inconsistencies within member states regarding the status of blood products. Blood and blood components were added to the 18th core list of the World Health Organization (WHO) Model List of Essential Medicines (EMs) in 2013.¹³ EMs are those that satisfy the priority healthcare needs of the population. The list is especially important as it is frequently taken as the basis for decisions in matters of healthcare policy and resource

allocation, as well as in questions of investments concerning the governance of blood systems in particular.

Added value

- The Directives were responsible for harmonizing the blood transfusion schemes in member states and helped to achieve overall self-sufficiency within the EU. The transposition of Directives into national legislation created EU-wide uniformity. At the regional level, an inter-regional imbalance in the quantity of norms and regulations can lead to fragmentation, with potentially harmful effects on the drive toward harmonization.

Non-remuneration and the ban on financial gain

Non-remuneration and the ban on financial gain are two discrete concepts: the former applies to individuals and the latter to states and organizations. They are, however, closely related, given that both derive from the principle asserted in numerous documents, including the Oviedo Convention. The 20th anniversary of the Oviedo Convention represents an opportunity to extend the horizon of the EU to the 47 Council of Europe member states. Article 21 of the Convention states that: “The human body and its parts shall not, as such, give rise to financial gain.”¹⁴ The Convention is recognized as an authoritative text, even though it has not yet been ratified by all the member states of the Council of Europe.¹⁵ Italy has ratified the Convention but to date has not deposited the relevant legislation with the Council,¹⁶ and it is therefore not formally binding.

The principle of non-remuneration is also cited in other Council of Europe documents, such as the Recommendation 95-15, which 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.”¹⁷

Other respected institutions have also unequivocally recognized these two principles of non-remuneration and the ban on financial gain. The WHO, for instance, has made several pronouncements on the subject, including the Melbourne Declaration¹⁸ and the Rome Declaration.¹⁹ Article 3 of the EU Charter of Fundamental Rights affirms “the prohibition on making the human body and its parts as such a source of financial gain.”²⁰

The periodic reports published by the EU Commission provide an overview of the situation in Europe regarding the non-remuneration of blood donations. The most recent report²¹ notes that in almost every country, donation promotion activities are the main actions taken to increase supply.

Although in the large majority of countries, the principle of voluntary unpaid donation (VUD) is mandatory at national level, the relevant legislations often refer to an “encouragement” or to a “strong recommendation.” The practical application of the VUD principle varies across the Union: certain practices are perceived as compensation in 1 country and as incentives in another. According to the report, “(i)t is common practice to provide refreshments to donors and to give them small tokens such as pin badges, pens, towels, t-shirts and mugs.”²¹ Moreover, in many member states “donors have their travel costs reimbursed and get time off work in the public and private sector.”²¹ A few states give donors a fixed payment that is not directly related to actual costs incurred. Only a few states have national guiding principles to define what form of compensation or other practice is allowed and under which circumstances.

In the report “Human bodies: donation for medicine and research,” the Nuffield Council²² proposed a “ladder” with six levels of intervention to encourage donations. The lower four rungs of the ladder are “altruistic” interventions, while the top two rungs are “non-altruistic-focused.” According to the report (which sparked considerable controversy²³) where a healthcare need cannot be satisfied through altruistic interventions, the possibility of non-altruistic-focused interventions should be considered.²²

There can be no question that it is not only legitimate, but also proper to reimburse any costs incurred by donors (eg, as recognized in Article 1 of the Code of Ethics for Blood Donation and Transfusion of the International Society of Blood Transfusion²⁴) as well as by institutions (as acknowledged, for instance, in the 5th of the World Health Organization’s Guiding Principles on Human Cell, Tissue and Organ Transplantation²⁵).

According to Farurgia and Del Bo “there are certain contradictions between the principle of non-commercialisation, the enormous movements of money inevitably involved in centralised blood systems, and the need to make the most of the system (...). (F)rom the ethical point of view these contradictions could be at least partially mitigated.”²⁶ Their reflections clearly aim to legitimize the collection of paid plasma and the activities of the wider commercial industry within the ISBT Code. The authors argue for a paradigm shift whereby the patient is placed at the center of all decisions and processes. However, “the proposed approach fails to recognise the unique aspect of donation whereby one individual provides for another with no direct personal benefit.”²⁷

The well-being of the numerous patients who could or do benefit from plasma-derived medicinal products (PDMPs)

deserves particular attention. Currently, almost 70% of the plasma from which PDMPs are derived is provided by donors who receive monetary compensation, while a large number of patients worldwide have no, or at best suboptimal, access to these products. Some authors have suggested it is time to re-think whether an absolutist position against compensation is still relevant or would be judged appropriate if it were evaluated using a risk-based decision-making approach.²⁸

It must be recognized that transfusions and transplants involve substantial flows of money: it is estimated that the annual spending throughout the EU on blood, tissues, and cells amounts to 6 billion euros, with another 3 billion euros on bone marrow transplants, while the market value of plasma-derived products is estimated at 4 billion euros.¹

In view of the above, it is useful to identify a few criteria that should be clearly articulated during the review of the Directive:

With regard to donors

- The human body and its parts must never, in any circumstances, give rise to financial gain. The donation of blood must be voluntary and should not be associated with any form of payment.
- The notion of “non-remuneration” does not exclude the possibility of offering legitimate “reimbursements” to donors. A clear and impassable red line must be established between legitimate forms of reimbursement (for expenses incurred or loss of earnings) for donors and any benefit of whatever nature (not only financial) associated with the donation. Reimbursements should be limited strictly to actual costs incurred or earnings lost and directly associated with the donation.
- The possibility of compensation for possible damages directly attributable to a donation should be allowed.
- No form of compensation for any inconvenience associated with a donation is admissible, as this could conceal the recruitment of “volunteers” and, consequently, the exploitation of vulnerable groups of individuals.
- The offer of favorable rates to donors for healthcare services not associated with donations is not admissible.
- No types of incentive/reimbursement should be perceivable as concealing forms of payment; they should therefore not have a cash value and not be transferable.

With regard to the costs associated with procedures

- The process of donation calls for recourse to professional personnel and appropriate procedures. Both the aspects

should be carefully regulated and paid for at a fair price. The legitimate costs associated with procurement and other activities necessary to guarantee the safety, quality, and efficacy of the materials used should be properly covered.

- Costs associated with the storage and, where appropriate, processing (chiefly in the case of cells and tissues) of materials should be met by the end user institutions.
- The professionals involved in these procedures (whether in public or private institutions) should not derive any benefit directly from their participation.

Another aspect involved is that of the possible marketing of products derived from voluntary blood donations. The Belgian Superior Health Council²⁹ noted in its comments on the draft for the road map¹ that the existence of flows of money verging on trade cannot be denied. Concern has also been expressed by the Belgian Federal Agency of Medicines and Health Products³⁰ and other institutions.

The problem also arises in a similar manner in the field of biotechnology, where regulations apply from the moment a patent is granted. The Organization for Economic Cooperation and Development, for instance, recognizes in the “Guidelines for the licensing of genetic inventions” that “License agreements should define the roles and responsibilities of the parties in the commercialisation, if any, of the products and services arising from the use of the licensed genetic invention.”³¹

It must be acknowledged that, as a general rule, blood, in common with other materials of human origin (eg, bone parts removed during surgery) can be used to derive products with a marketable value. Even though the donor may no longer be identifiable, the origin of the material is still an act of voluntary generosity. Elements or products derived from the human body should therefore be used only for therapeutic purposes or for biomedical research: their for-profit use by the (non-medically driven) cosmetics industry should not be allowed. In addition, in the event that the use of human biological material generates some form of financial gain, this should be used principally to benefit the community at large (national health services).

Nonetheless, there may be occasions when commercial spillover effects cannot be excluded. The development of therapeutically effective products from donated human biological material that is unusable and therefore destined to be discarded satisfies two of the basic principles of bioethics: 1) beneficence (therapeutic principle), which recognizes that medicine is essentially a matter of therapy, in other words, its aim is to defend and promote health; and 2) justice, which is rooted in sociality and encourages the expression of medicine

as a service intended for the general good. Such a product is cord blood that is unsuitable for transplantation but which can be used to produce platelet gel³² and other products³³ with considerable therapeutic potential.

The possibility that products derived from donated human biological materials may enter commercial circuits is not excluded, for example, by the Council on Ethical and Judicial Affairs of the American Medical Association in its Code of Medical Ethics³⁴ and in the document “Who should profit from the economic value of human tissue? An ethical analysis.”³⁵ In such circumstances, the Council on Ethical and Judicial Affairs calls for the mandatory compliance with specific requisites, including, among others, information and consent, possibility for patients to share in the profit, absolute guarantee that good clinical practice is in no way influenced by commercial objectives.

Conclusion

During revision of the Directives, as well as in additional texts that will be published in the future, the following ethical criteria should always be reasserted and applied:

- consent to donation should always be given in total freedom and in full compliance with current legislation;
- the rules regarding fixed costs, compensation, and reimbursements should be addressed in EU Directives and applied uniformly in all member states;
- legislators and national authorities should encourage a culture of donation aimed at spreading awareness that numerous lives can be saved by a simple altruistic gesture;
- some of the states that are signatories to declarations of principle regarding the non-remuneration of donations such as those mentioned above however provide for forms of reimbursement that more or less explicitly amount to payments. In these cases, the term “donation” should no longer be used, for the sake of consistency; if an action is remunerated, it is not a donation;
- the possibility of establishing partnerships between the public and private sectors for the marketing of therapeutic products outside national healthcare services could be explored.

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Disclosure

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