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# **Principles for global consensus on the donation and management of blood, blood components and medical products of human origin**

## **Report by the Secretariat**

1. Medical products of human origin are defined as substances that are derived wholly or in part from the human body and intended for clinical application.<sup>1</sup> Source components in the human body range from organs, tissues, blood, cells and gametes to breast milk, hair, nails, urine and faeces. Medical products of human origin often represent the most beneficial and cost-effective therapies for several life-threatening or debilitating conditions. They have also enabled the birth of many much-wanted children.
2. Such medical products are fundamentally different from other medical products because they depend on the donation of biological materials from living or deceased persons. Concern for the dignity and human rights of donors, in particular their own rights to health and the security of their own person, requires high ethical standards in the procurement of biological materials for use as medical products of human origin. Particular care must, therefore, be taken to ensure that donors are not subject to exploitation, coercion or abuse.
3. The human origin of these medical products also entails risks to public health. The recurrent emergence of diseases, such as the recent Zika virus outbreak, requires systems of production of medical products of human origin that can predict and mitigate transmission of known or unknown pathogens and swiftly be adapted to new threats. Essential safety mechanisms include appropriate donor screening and testing, techniques that inactivate pathogens or render them less pathogenic, and adequate traceability of medical products of human origin, so that sentinel events of disease transmission can be promptly investigated and linked to specific products, source individuals and recipients, enabling the development of new risk containment and mitigation strategies, including rapid product recalls.
4. Considerable inequalities remain in access to medical products of human origin, even blood and blood components, between and within countries and regions. For instance, of the 112.5 million whole blood donations collected globally, about half are collected in high-income countries, home to just

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<sup>1</sup> Noël L, Martin DE. The exception of medical products of human origin: towards global governance tools?. In: Rainhorn JD, El Boudamoussi S (eds). *New cannibal markets: globalization and commodification of the human body*. Paris: Editions de la Maison des sciences de l'homme, 2015, p.383.

19% of the world's population. Lack of universal health coverage is a major factor contributing to inequalities of access to medical products of human origin. Regrettably, individuals who lack access to their benefits are sometimes those most likely to be exploited as sources of biological materials used in medical products of human origins, in which instances protective measures against the trafficking of products or donors are seldom adequate.

5. The demand for medical products of human origin is growing with the emergence of new therapeutic applications, improved access to health care in some regions, and changing demographics of potential donor and recipient populations, such as ageing and increased burdens of chronic diseases. Failure to prevent the progression of many of the diseases that lead to the need for medical products of human origin, such as trachoma causing corneal blindness and diabetes resulting in kidney failure, means that the growth in demand for these products continues to outpace the increase in their availability.

6. The Health Assembly has endorsed ethical principles and governance mechanisms<sup>1</sup> and the Secretariat, WHO collaborating centres and nongovernmental organizations have issued further guidance for facilitating implementation of those principles and mechanisms. Nevertheless, the available guidance is somewhat fragmented and generally oriented towards a number of specific products (e.g. blood and organs/tissues/cells).

7. In decision EB136(2) (2015), the Board “requested that the Director-General convene consultations with Member States and international partners, to support the development of global consensus on guiding ethical principles for the donation and management of [...] medical products of human origin; good governance mechanisms; and common tools to ensure quality, safety and traceability, as well as equitable access and availability, as applicable, to result in a document to be submitted to the Seventieth World Health Assembly for its consideration.”

## **PROCESS FOR BUILDING GLOBAL CONSENSUS**

8. Pursuant to the request in decision EB136(2), the Secretariat elaborated a framework of principles on donation and management of medical products of human origin, in collaboration and consultation with a large and broad group of independent experts and scientific societies. The document was based on previous guidance, identifying ethical principles and governance mechanisms valid for all types of medical products of human origin, and proposed a globally harmonized approach to governance using shared tools. The goal was to foster consistency of ethical practices in order to strengthen the overall safety, quality and availability of medical products of human origin.

9. That draft framework of principles and policy options was opened on a dedicated web page on the WHO extranet for a public consultation between 22 September and 15 October 2016. All Member States, WHO collaborating centres, non-State actors in official relations with WHO, other institutions and stakeholders, such as scientific and professional societies, patients' associations and civil society

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<sup>1</sup> Resolutions WHA28.72 (1975), Utilization and supply of human blood and blood products; WHA58.13 (2005), Blood safety: proposal to establish World Blood Donor Day; WHA63.12 (2010), Availability, safety and quality of blood products; and WHA63.22 (2010) Human organ and tissue transplantation, in which the Health Assembly endorsed the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.

members active in the field were invited to provide comments. A full report of the consultative process and the results will be available on the WHO website in early January 2017.<sup>1</sup>

10. All the input provided through the consultative process has been analysed and taken into consideration in drafting the latest version of the framework of principles, which follows.

## PRINCIPLES

11. The following 10 principles for promoting ethical practices in the donation and management of medical products of human origin are propounded.

**Principle 1. Governments are responsible for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility includes the obligation to develop and enforce regulations to ensure the maximum possible level of safety, quality and efficacy, both within and across national borders.**

Governmental authorities, as representatives of the public, are responsible for ensuring the ethical and effective procurement, distribution and use of medical products of human origin. This responsibility stems from not only governments' core duty to protect and promote public health, but also their role in protecting the fundamental rights and freedoms of individuals, which may be endangered by unethical practices of procurement or distribution. Fulfilling this responsibility depends on the effective functioning of health care services and systems, as well as the creation and enforcement of regulations to ensure a high level of safety, quality and efficacy within and across national borders.

**Principle 2. Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin.**

In principle, if all members of society have an equitable share in the benefits derived from medical products of human origin, they should have a shared responsibility in helping to meet the need for those products, through donation when possible. Health authorities have a responsibility to establish systems and organizations that reduce or eliminate barriers to donation of and access to medical products of human origin, thereby promoting equity. Individuals and groups should be neither denied the opportunity of donating biological materials for use in medical products of human origin where this exists, nor encouraged to donate where the opportunity does not exist, except where clearly justifiable reasons apply. Where a prospective donation may be unnecessary, for example if there is a surplus of a particular medical product of human origin or it is unduly harmful for the prospective donor or intended recipients, health care providers should not accept the offer to donate (in the case of a surplus) or should not proceed with the procurement (in case of risk to the donor).

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<sup>1</sup> <http://www.who.int/service-delivery-safety/en/>.

**Principle 3. Outside clinical research and for the advancement of science, medical products of human origin should be used only in situations of proven efficacy and in the absence of alternative and affordable therapies with a comparable or more favourable balance of risks and benefits.**

Responsible stewardship of medical products of human origin requires using these exceptional health resources as efficiently as possible, thereby minimizing the burden of donation on individuals and maximizing access to the necessary products. The efficient use of medical products of human origin requires good clinical practice and management within the broader health care system. Human biological materials should be procured only when necessary to meet the prospective needs of recipients or, with the consent of donors, for other purposes such as research or training that may serve to accomplish donors' overarching goals of contributing to improving human health.

**Principle 4. Biological materials from living persons for use as medical products of human origin should be taken only with the donor's prior informed and voluntary consent. When biological material from a deceased person is to be used as medical product of human origin, it is imperative to verify that the individual has provided his or her prior consent or has not expressed objections to be a donor, as mandated by national laws.**

Biological materials should not be taken from living persons for use in medical products of human origin without the individual's voluntary and informed consent. The requirement for consent protects potential donors against violation of their bodily integrity and respects their interests in making important life choices in accordance with their values and personal goals. In the absence of effective processes for informing potential donors and obtaining their consent, individuals may be vulnerable to coercion or exploitation, such that they feel forced to donate or agree to donate against their personal preferences and values. On the other hand, providing clear and adequate information to prospective donors may increase their will to donate and therefore often expand the pool of potential donors.

As recognized in the WHO guiding principles on human cell, tissue and organ transplantation,<sup>1</sup> any regulation on requirements to obtain explicit consent to retrieve biological materials from deceased persons "depends upon each country's social, medical and cultural traditions, including the manner in which families are involved in decision-making about health care generally." However, even in countries that do not require explicit consent for deceased donation, no biological materials should be removed from a deceased person if the person, while alive, filed an objection to donation with an identified office or otherwise definitively voiced an objection to donation. Countries that do not require explicit consent for the retrieval of biological materials from deceased persons should ensure that the public is fully informed of this policy, and that individuals who do not want their biological materials retrieved upon death have an easy way to express this objection.

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<sup>1</sup> [http://www.who.int/transplantation/Guiding\\_PrinciplesTransplantation\\_WHA63.22en.pdf?ua=1](http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf?ua=1) (accessed 8 December 2016).

**Principle 5. Policies governing payment to persons who provide biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals and promote equity in donation. The best way to achieve these goals is to adhere to a policy of financial neutrality, in which persons who provide their biological materials for use as medical products of human origin are paid an amount sufficient to ensure that they neither benefit nor lose financially as a result of the donation. Countries that choose not to apply the principle of financial neutrality for specific biological materials should ensure that the burden of donating these materials does not fall primarily on economically disadvantaged groups.**

When payment is provided in exchange for consent to procure biological materials from a living person or deceased body, or to obtain materials that have been previously procured, and that payment is intended to leave the person authorizing procurement or providing these materials with financial gain, the human body and its parts effectively become a source of income. Financial gain from the human body is ethically problematic for several reasons. It increases the risk of coercion and exploitation of potential living donors; it results in the inequitable distribution of the burden of donation, which in turn may result in stigmatization of donation; it may encourage potential living donors to assume a higher level of risk in the process of donation; it may also result in the recruitment of donors who are at a higher risk of harm or whose materials may present higher risks for recipients; it may impair trust in the integrity of the determination of death and deceased donation; it may negatively impact voluntary and unpaid donation; it may represent a perverse incentive for the production of more “lucrative” medical products of human origin to the detriment of those for which there is greater clinical need; and it may also promote inequities in the distribution of medical products of human origin. The notion that the human body or its parts can be a source of financial gain further threatens respect for the fundamental dignity of human beings, namely a recognition of the inherent, unique and non-transferable value of each individual.

This principle is consistent with payments, reimbursement or coverage of reasonable costs associated with donation, such as transportation expenses and documented lost wages. Just as donors should not benefit financially as a result of donation, neither should they suffer financial injury as consequence of donation.

Governments in countries in which the principle of financial neutrality is not currently being applied for specific products are encouraged to explore the possibility of a future transition, while ensuring that systems are in place to minimize the risk that the burdens of donation do not fall primarily on economically disadvantaged populations. These safeguards could include tracking systems to limit how frequently an individual can serve as a donor, and adequate insurance coverage for donors, irrespective of any payments made to them.

**Principle 6. Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.**

Prospective and actual donors of various human biological materials face a range of physical and psychosocial risks. These may be associated with the evaluation process, procurement or long-term sequelae of donation. Risks vary according to the type of donation, the individual and the context in which donation occurs. Improvements in donor health care and advanced procurement procedures have almost eliminated or significantly reduced some risks. However, new risks have emerged for certain practices, as a result of research or new procurement

processes. Risks cannot always be accurately predicted, and may evolve during the lifetime of a donor.

**Principle 7. Information about the relevant product, including its human origin, should be routinely provided when offering medical products of human origin to prospective recipients, without compromising the confidentiality of the donor's identity.**

In addition to information about the potential risks and benefits of using specific medical products of human origin, which should be provided to prospective recipients as part of routine consent procedures, prospective recipients should also be explicitly informed that the clinical product they are to receive is derived wholly or in part from human biological materials. Recipients of medical products of human origin should also be informed about the policy on donation in their country or local health care jurisdiction. This procedure constitutes an acknowledgement of the donors and promotes societal awareness of the necessity of donation.

**Principle 8. Equity in access to the benefits of medical products of human origin should be promoted by sustained efforts to remove barriers to access. Any waiting lists and allocation systems that are developed for medical products of human origin should be based on clinical criteria and ethical norms, not considerations of financial or social status.**

Where there is a lack of particular medical product of human origin to meet clinical need within society, systems should be implemented to ensure equity in allocation of available products, such that unavoidable prioritization during distribution is fair and necessary. Achieving equity in the allocation of medical products of human origin requires attention to the criteria used in establishing waiting lists and allocation protocols, as well as to barriers in access to health care services more generally. Although directed donation of biological materials has the potential to undermine equity in access to the benefits of donation, some directed-donation programmes may actually reduce the societal burdens of unmet needs for medical products of human origin.

**Principle 9. In order to minimize the risk of harm to donors and recipients and to protect the stability and sustainability of services for medical products of human origin, all steps in the development and use of medical products of human origin should be fully traceable and subject to effective quality-management systems and vigilance and surveillance programmes.**

Routine monitoring and evaluation of systems and processes pertaining to medical products of human origin provide information that guides ethical practice and policy, informs decision-making by the public, professionals and policy-makers, and fosters continuous clinical and scientific improvement. Likewise, quality-management systems and vigilance and surveillance programmes promote timely responses to new or recurrent threats and enable the application of new knowledge to improve the safety and quality of products, thereby protecting donors, recipients and public health.

**Principle 10. The organization and delivery of activities related to medical products of human origin, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the confidentiality of donors and recipients is always protected and adheres to national laws.**

The provision of adequate information and data enables the public to make informed choices about donation and use of medical products of human origin. Such transparency and mechanisms to ensure the traceability of medical products of human origin are not incompatible with the protection of confidential information concerning individual donors and recipients of such medical products.

In instances in which biological material is used for the production of trademarked pharmaceuticals or medical devices, transparency must be ensured, so that the commercial status of those medical products of human origin is clearly and openly documented and available to society, and hence to prospective donors and recipients. Public trust in the systems that manage the procurement, distribution and use of medical products of human origin encourages participation in donation opportunities. This public trust must therefore be established and maintained and is best achieved through a transparent presentation of policies and practices and reporting of outcomes.

## **KEY CONSIDERATIONS FOR IMPLEMENTATION**

12. Different types of medical product of human origin may require different operational systems and regulatory oversight adapted to their specificities. Although the principles set forth apply to all medical products of human origin, the manner in which countries implement these principles may differ depending on the type of product in question. For example, countries may want to adopt particular policy mechanisms in the field of organ transplantation (such as the use of national waiting lists and allocation algorithms), without necessarily extending those mechanisms to other medical products of human origin such as blood or gametes.

13. Consolidation of regulatory oversight and national coordination of services providing different types of medical products of human origin, for example blood, tissues, organs and gametes, may be beneficial through economies of scale, optimal use of professional expertise or consistent communication with the public. Services related to the procurement, manufacture and provision of medical products of human origin and their coordination and regulatory oversight should be integrated in the health system to ensure smooth and efficient communication with users of those products and regulators of other types of health products.

14. Some medical products of human origin, specifically those that undergo an extensive manufacturing process such as plasma-derived medicinal products, may be regulated as pharmaceuticals, whereas others, such as tissue-derived products used in orthopaedics, may be regulated independently or as medical devices. Regardless of how particular medical products of human origin are classified, all forms of regulation should explicitly address requirements specific to those medical products, such as donor protection. In practice, close collaboration among regulators internationally and among regulatory bodies within countries, and oversight of the various steps from procurement of the human biological material through to clinical application of the final product will be necessary to ensure efficiency and maintenance of standards across the whole process of preparing and using medical products of human origin.

15. Each principle should be further elaborated with strategic approaches and potential policy options and interventions for its attainment. The appropriate mix of policies and interventions to be used at the country level will need to be designed and developed according to the local context, values and priorities. Governance mechanisms are generally valid for all medical products of human origin, including: legislation and regulation; policy and strategic planning; financial sustainability; traceability; vigilance and surveillance; transparency; public engagement; and crisis response plans. The Secretariat is able to provide support to Member States in the implementation procedure through guidance on the basis of input from technical consultations, literature reviews and expert opinion.

**ACTION BY THE EXECUTIVE BOARD**

16. The Board is invited to note this report and provide further guidance on the draft framework of guiding principles.

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