

#### FÉDÉRATION INTERNATIONALE DES ORGANISATIONS DE DONNEURS DE SANG INTERNATIONAL FEDERATION OF BLOOD DONOR ORGANIZATIONS FEDERACIÓN INTERNACIONAL DE ORGANIZACIONES DE DONANTES DE SANGRE

#### The IFBDO/FIODS and its mission

The IFBDO (or FIODS, in French) is the International Federation of Blood Donor Organizations, the official international network of national donors' associations and federations working for the promotion of voluntary, anonymous, regular, non-remunerated (VNRD) blood and plasma donation.

The Federation was founded in 1955 and nowadays includes more than 80 members in 4 continents, representing more than 18 million of blood donors in the world.

The main goal of IFBDO is to reach and maintain self-sufficiency of blood and blood components for all the patients in the world who need transfusions or blood and plasma derived medicines, ensuring the promotion and safety of both receiving patients and donors.

# The act of donation and the importance of voluntary and non-remunerated blood donation (VNRD)

We firmly believe that voluntary, anonymous, non-remunerated, regular donors are the "safest" allies for themselves and especially for the patients.

Donation is an act of solidarity for the benefit of others and contributes to social cohesion and civic engagement.

Donated blood (and plasma) should be considered as a public, ethical, strategical and community good in order to assure the dignity of the donor and of their donation and not as a commodity to meet others' ends.

Therefore, all the forms of "compensation" for donors (as well the reimbursements given for generic "inconveniences" related to the act of blood donation) should be carefully avoided, since they could easily go beyond the principle of "financial neutrality" that should be related to the volunteering activities and hide forms of remuneration. If it's remunerated, it is not donation.

Most EU countries have opted for voluntary non-remunerated blood donation. VNRD is also recommended by the WHO and the Council of Europe, ISBT, the Red Cross, just to recall some of the major health institutions.

Blood donation is indeed a matter of health and human rights: donor rights and patient rights (Charter of Fundamental Rights of the EU, art. 3; Oviedo Convention on Human Rights and Biomedicine, art. 21, which forbids all profit making from the human body or parts of it).

The principle of voluntary AND non-remunerated donation (VNRD) needs to be further stressed and specified, as it represents one of the main guarantees for the safety and quality standards for blood and blood components, as outlined in the legislation under review, and for donors' and patients' protection.

## Donor community: the role of IFBDO/FIODS and donor organisations in blood donation

Associations are – in many cases – responsible for donor recruitment and donor retention (regular donors) and can be very effective in this mission thanks to their proximity with the donors.

Associations play a strategic role not only for these major tasks, but also for <u>donor education</u> and in raising awareness about the importance of voluntary non-remunerated donors in public health systems and in promoting the culture of solidarity, prevention and healthy lifestyles (in a complementary way to the actions of health authorities).

At this regard, we recall the European Parliament resolution of 27 October 2016 on European Voluntary Service and the promotion of volunteering in Europe, which recognizes that «volunteering has a value and importance as one of the most visible expressions of solidarity, which promotes and facilitates social inclusion, builds social capital and produces a transformative effect on society, and that volunteering contributes both to the development of a thriving civil society, which can offer creative and innovative solutions to common challenges, and to economic growth».

We stress the need for a wider recognition of voluntary organizations in the field of blood and plasma donation, their role in the transfusion system in cooperation with EU & national health institutions, and their work for donors' recruitment and retention.

#### The blood collection system in the EU

Directive 2002/98/EC (art. 20) encourages Member States to collect 100% of donations of blood and plasma from voluntary and unpaid donors but does not include any obligation: this legislative void leaves room for various interpretations which can be dangerous for the stability of the blood supply from VNRD in Europe.

Europe should adopt a proper strategy and strong actions to reduce its dependence from plasma-derived medicinal products (PDMPs) produced from plasma imported from countries where the principle of VNRD is not respected.

We should be also very careful to admit distinctions between blood and plasma donation and their respective regulation, to avoid the allowance of forms of donor compensation and so the related risk of eroding the current VNRD blood donor base.

We stress the relevance of a comprehensive, coordinated and long-term oriented approach, based on the idea of donated blood (and blood components) as a public, ethical, strategical and community good.

The European health programme should include measures to enhance blood safety and sufficiency of supply and to support member states in promotion of recruitment and retention of voluntary non-remunerated blood donors.

#### **Donor protection and selection criteria**

We are convinced that any kind of revision of donor eligibility and donor protection criteria must be supported by accepted and regularly reviewed scientific evidence.

In addition to that, we underline the opportunity to set basic and common standards for blood and blood components collection in order to ensure the donors' and recipients' safety.

Furthermore, the IFBDO is committed to develop proper <u>donor care</u> in all European countries, This means actively working for the donor health protection; feedback and recognition to meet expectations; let donors understand the ethical importance of their gift as an expression of community participation in the health system, as also a way to increase donor retention.

The commission should in cooperation with the Council of Europe work for harmonizing the guidelines for blood donor deferrals in Europe, and make sure that the deferrals are done on rational medical grounds. Donor deferral should be based on rational decisions, based on the principle to harm neither donor nor patient, and there should be access to the scientific evidence leading to the deferral rules, so that interested donors can obtain this information.

The number of donor deferrals is very much influenced by the information-level of the donors. The blood services are obliged to inform the donors according to the European directive, but there should be data from different countries on deferrals rate and number of donors in quarantine. There is a need for additional obligatory information to all donors in Europe.

#### Working towards self-sufficiency in blood and blood components from VNRD

Finally, these are the final messages we would like the European Parliament, the Member States and the European Commission to consider:

- Voluntary, anonymous, non-remunerated, regular donors are the "safest" allies for themselves and especially for the patients, as well as for their communities;
- The EU legislation should recognize the nature of blood products supply as a life-saving service of general interest for the community as a whole;
- Clear definitions about VNRD and criteria about how to reach self-sufficiency on this basis should be adopted;
- We call for the empowerment of donor organizations: where donor associations are present, the coverage of needs tends towards self-sufficiency;
- o Thanks to the cooperation between health authorities and donor organisations, joint efforts should be put in place to enlarge the donor base;
- o Full traceability for all blood products should be implemented, with particular reference to the plasma-derived medicinal products (PDMP) labelling;

- We also underline the importance of scientific research and data collection about donor eligibility and donor protection criteria;
- O The European Parliament should call for a continued <u>reporting</u> from the European Commission in the progress of voluntary non-remunerated blood donation, as foreseen in Art 20,2 of Directive 2002/98, under which member states every three years must report on their progress towards achieving full voluntary non remunerated blood donation. The Commission should also inform to the Council and the Parliament of necessary complementary measures, it intends to take to achieve this goal.
- We urge the EU institutions to develop a coordinated approach and common projects/plans to reach self-sufficiency for blood and blood components and PDMPs from VNRD across Europe.

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