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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

2nd Report on Voluntary and Unpaid Donation of Blood and Blood Components

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1. INTRODUCTION

The principles governing voluntary and unpaid donation of blood and blood components are set out in article 20 of Directive 2002/98/EC[1]. It 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.*

Donors can give whole blood or just some components of the blood, e.g. plasma. During donations of blood components, the needed components are separated from the blood and the remainder is thereafter returned to the donors in a so-called apheresis process. Such apheresis donations take longer in time but can be organised more frequently. While plasma can be separated from whole blood after the donation, much plasma is obtained through apheresis (plasmapheresis).

Donated blood and blood components are essential bases for therapies, either as direct transfusions e.g. during surgery, or as starting materials for plasma derived medicinal products, e.g. to treat factor VIII deficient haemophilia patients.

In accordance with Article 20(2) of the Directive, Member States shall submit reports on the practice of voluntary and unpaid blood donation to the Commission every three years. The first report on the promotion by Member States of voluntary unpaid blood donations was published in 2006[2].

This Commission report is based on the Members States' responses to a report template on voluntary and unpaid donation of blood and blood components, which was sent to the Competent Authorities for blood and blood components during the spring of 2010. All Member States submitted a report to the Commission. In addition, Croatia and Norway submitted a report (in total 29 reporting countries). The main findings of this report have been presented to the Competent Authorities for blood and blood components[3].

This second report aims to provide an overview of the practice of voluntary and unpaid donation of blood and blood components in the EU, focusing on (1) legislative provisions/guidelines and policies, (2) incentives, (3) promotion, and (4) collection and supply. It should, however, be noted that although this report touches on areas related to pharmaceuticals, its focus is on blood and blood components[4].

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1 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 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.

2 COM(2006)217 final, Report on the promotion by Member States of voluntary unpaid blood donations.

3 http://ec.europa.eu/health/blood_tissues_organs/docs/blood_mi_20101027_en.pdf.

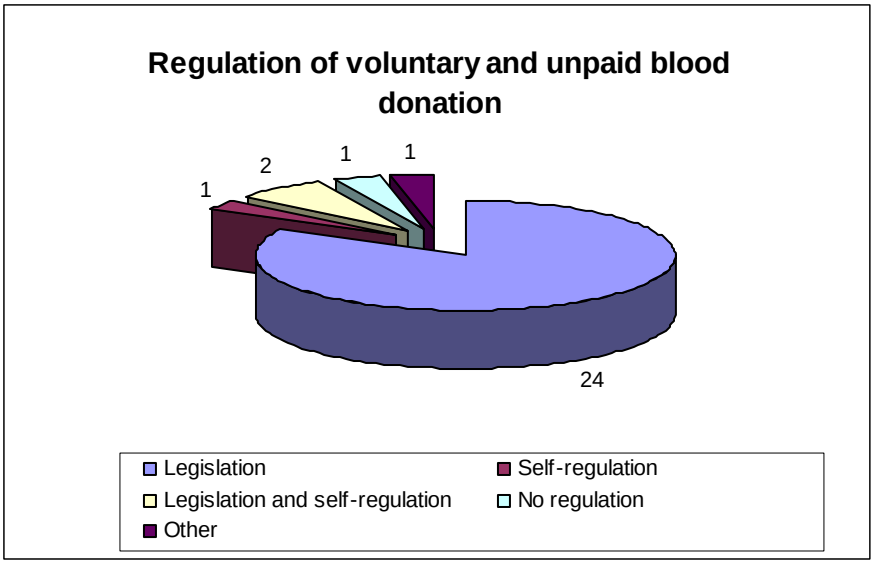
4 Directive 2002/98/EC defines blood as "whole blood collected from a donor and processed either for transfusion or for further manufacturing", and blood components as "therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods".

2. RESULTS

2.1. Legislative provisions, guidelines and policies

All but one of the reporting countries have some form of provisions (binding or non-binding) governing the principle of voluntary and unpaid donation of blood and blood components (Figure I).

Figure I



As shown in figure I, 24 countries have binding rules concerning voluntary and unpaid blood donation, laid down in national regulations (Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Poland, Romania, Slovenia, Slovakia, Spain, Sweden, Norway and Croatia). Hungary and the UK have a dual system with binding rules laid down by national regulations and rules set by the sector (self-regulatory), and in Malta, binding rules concerning voluntary and unpaid blood donation are set by the sector (self-regulatory). The Czech Republic has a non binding declaration in its national law (in line with Directive 2002/98/EC), while Ireland has no legislative provisions or guidelines governing the principle of voluntary and unpaid donation of blood and blood components.

These legal provisions and guidelines appear to have remained relatively stable over time. Since 2006, when the 1st Report on the promotion by Member States of voluntary and unpaid blood donations was issued by the Commission, the Czech Republic, Croatia and Sweden have changed their provisions on voluntary and unpaid blood donation. However, two countries (Czech Republic and Estonia) state that they are planning to change their existing legal provisions or guidelines.

Austria, Belgium, Bulgaria, Cyprus, Estonia, Finland, France, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden, the United Kingdom and Croatia have defined penalties for infringements of the legislative provisions on voluntary and unpaid donation of blood and blood components. None of these countries have imposed such penalties.

2.1.1. Replacement donors

A replacement blood donor could be described as a person who gives a replacement unit of blood only when a family member or friend requires transfusion.

Only 6 Member States have specific policies concerning the practice of replacement donors (Czech Republic, France, Hungary, Spain, Sweden and the United Kingdom). In these countries the practice of replacement donors is generally discouraged.

2.1.2. Trans-border blood donation

In certain parts of the EU, there seems to exist a practice of individuals donating blood and blood components outside their country of residence, e.g. in another Member State.

Six countries (Czech Republic, Estonia, Luxembourg, Poland, Sweden and Norway) report having some form of policy or guidelines concerning the practice of trans-border blood donation.

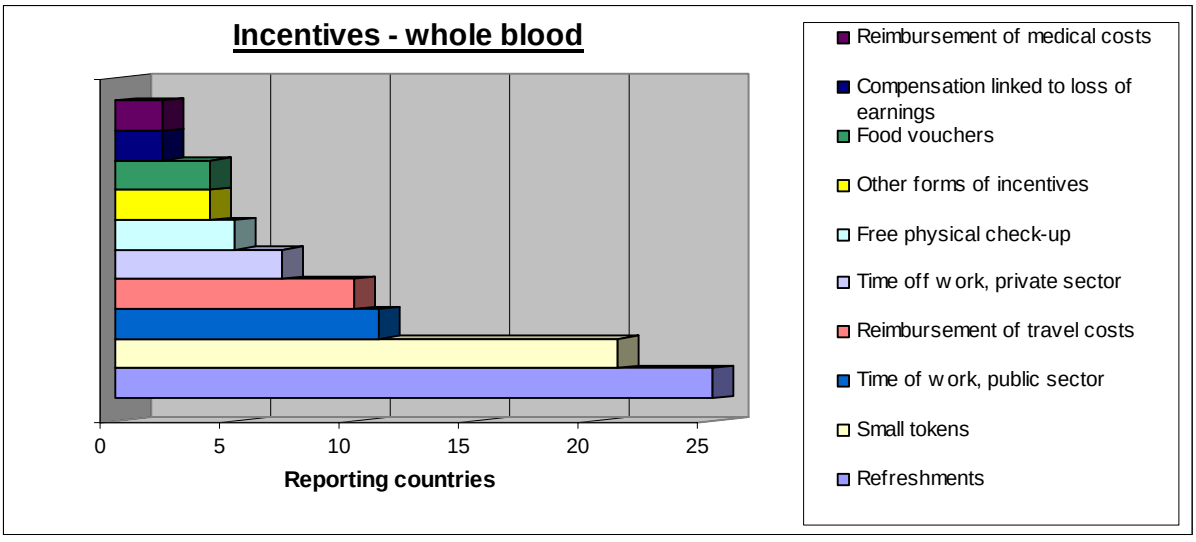
2.2. Incentives

Belgium, Bulgaria, Estonia, Finland, France, Germany, Greece, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Romania, Spain, Slovakia and the United Kingdom as well as Norway and Croatia (18 countries) reported some form of guiding principles concerning the possibility of giving incentives to donors of blood and blood components.

2.2.1. Incentives for whole blood donors

The following countries provide some form of incentives to whole blood donors: Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Romania, Spain, Slovakia, Slovenia, Sweden, the United Kingdom, Norway and Croatia (Figure II).

Figure II



As illustrated by the figure above, the most commonly used incentives in these 26 countries include refreshments, small tokens, such as mugs and t-shirts, time off work (in the public sector), and reimbursement of travel costs.

2.2.2. Incentives for apheresis donors

As regards apheresis (plasma, platelets…), the following countries provide some form of incentives to donors: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Romania, Spain, Slovenia, Sweden, the United Kingdom, Norway and Croatia (Figure III).

Figure III

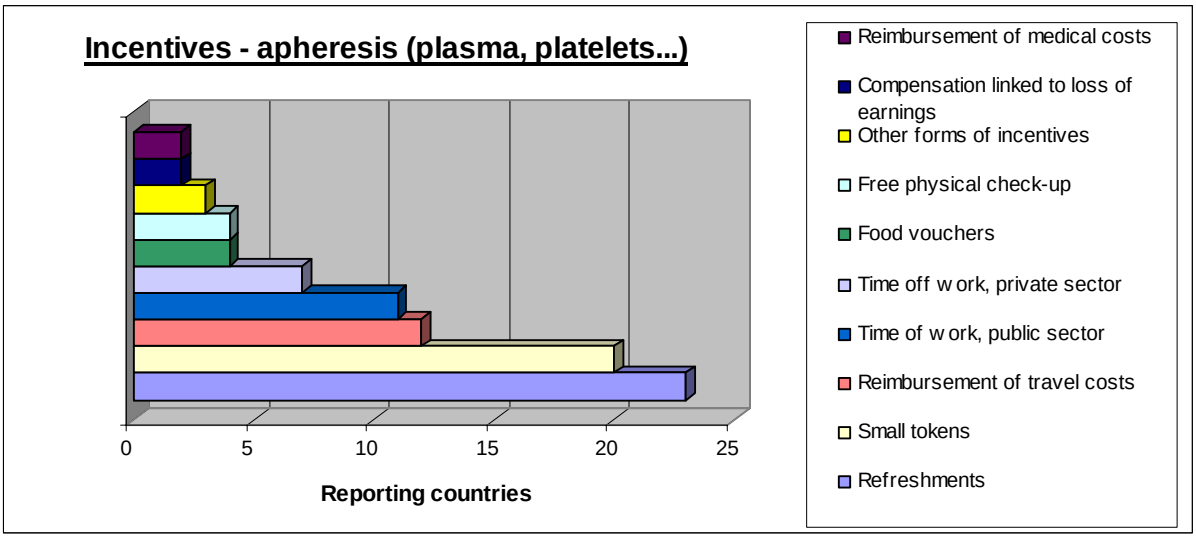


Figure III shows that the most commonly used incentives in these 24 countries include refreshments, small tokens, such as mugs and t-shirts, reimbursement of travel costs and time off work (in the public sector).

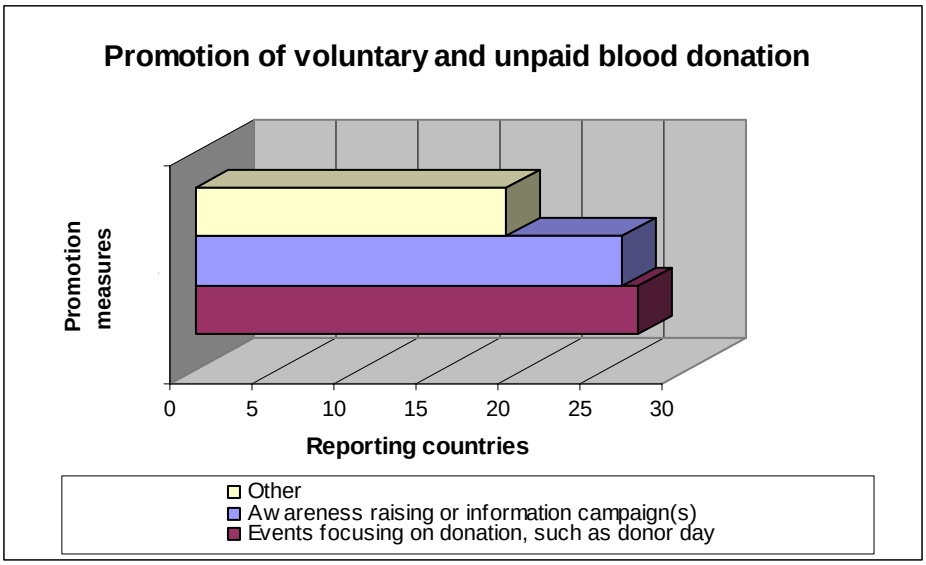
In sum, the undertaken study indicates that there are no major differences in incentives for whole blood and apheresis donors in the EU, Norway and Croatia.

The values of these incentives are determined by governments and/or operators in the reporting countries. For whole blood, this value is set by national or local governments in 10 countries, by operators/blood establishments in 10 countries, and by a combination of both or other in 5 countries. Similarly for apheresis, the value of incentives is defined by national or local governments in 10 countries, by operators/blood or apheresis establishments in 9 countries, and by a combination of both or other in 4 countries. No data was provided by Ireland on this point.

2.3. Promotion

The following countries have undertaken some form of measures to promote voluntary and unpaid blood donation: Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden, the United Kingdom, Norway and Croatia.

Figure IV



As demonstrated by the figure above, the most commonly used measures to promote voluntary and unpaid blood donation in the EU, Croatia and Norway are events focusing on donation, awareness raising and information campaigns. More specifically, the listed measures include: (1) public advertisement, (2) personal phone calls, e-mails, letters and text messages to donors, (3) concerts and other performances, (4) media events, (5) campaigns and other social events (nationally, regionally and locally) e.g. at the World Donor Day, (6) online information and campaigns, booklets and flyers, (7) seminars and lectures at schools, universities and churches, (8) student visits to blood establishments, and (9) other measures in cooperation with blood establishments, associations and other organisations.

21 of the reporting countries have defined target groups for their promotion activities. The main target groups identified are young people, students, military personnel and first time donors.

2.4. Collection and supply

2.4.1. Collection

The collectors/suppliers of whole blood and plasma are predominately public in the 29 countries participating in this survey.

25 countries report that the main collectors/suppliers for whole blood are public or non for profit, whereas 1 country has private suppliers/collectors and 3 countries have a mixture of public-private and/or other collectors/suppliers. The following countries report having public or non for profit collectors/suppliers: Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, France, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Malta, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden, the United Kingdom, Norway and Croatia. In addition, Austria report having private suppliers/collectors and Finland, Germany and Lithuania have a mixture of public-private and/or other collectors/suppliers.

Similarly for plasma, 23 countries have public or non for profit collectors/suppliers, whereas 6 Member States have private or a mixture of public-private and/or other collectors/suppliers. The following countries report having public or non for profit collectors/suppliers: Belgium, Bulgaria, Cyprus, Denmark, Estonia, France, Greece, Hungary, Ireland, Italy, Luxembourg, the Netherlands, Malta, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden, the United Kingdom, Norway and Croatia. In addition, Austria, Czech Republic, Finland, Germany, Latvia and Lithuania have private or a mixture of public-private and/or other collectors/suppliers.

Furthermore, the participants in this study were asked whether they provide financial or other incentives for the collection of blood and blood components, e.g. to blood establishments, hospitals and health care personnel. About 10% of the countries report giving some form of incentives to collectors/suppliers of blood and blood components.

2.4.2. Plasma fractionation

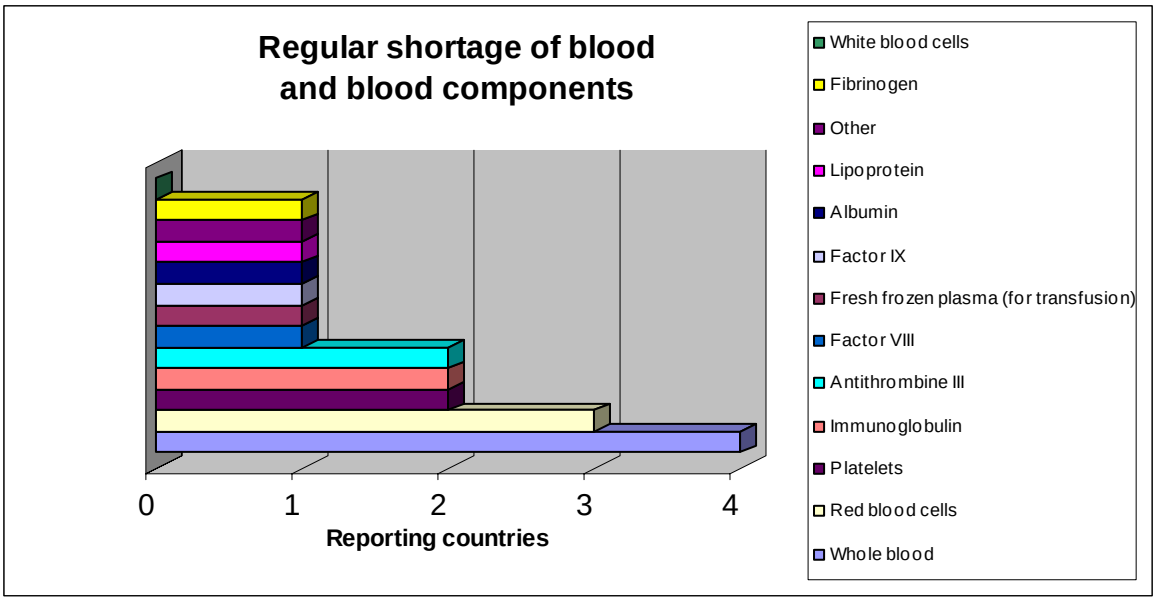
Plasma fractionation refers to the processes of separating the various fractions out of blood plasma. It includes manufacturing steps that are subject to pharmaceutical legislation and results in plasma derived medicinal products.

About half of the 29 reporting countries have the capacity (pharmaceutical plants) for such plasma fractionation (Austria, Belgium, Bulgaria, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, Slovakia, Sweden, the UK and Croatia). In these countries, about 71% of the actors are private and the remaining 29% are public.

2.4.3. Supply of blood and blood components

In the undertaken study, the participating countries were asked whether they have experienced regular shortage of blood and blood components, and in particular for whole blood, fresh frozen plasma (for transfusion), red blood cells, white blood cells, platelets and plasma fractions, such as immunoglobulin, factor VIII, factor IX, albumin, lipoprotein, fibrinogen and antithrombine III (Figure V).

Figure V



In accordance with this figure, it appears that few countries have experienced regular shortage of blood and blood components, ranging from around 14% (for whole blood) to 0% for white blood cells.

2.4.4. Clinical use

About 75% of the responding countries have policies in place to contain or ensure the effective clinical use of blood and blood components (Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Portugal, Romania, Spain, Sweden, the U.K. and Norway).

2.4.5. Self-sufficiency

The following countries have policies in place to endeavour to promote self-sufficiency of blood and blood components: Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Spain, Slovenia, Sweden, Norway and Croatia. These policies appear to have remained more or less stable over time. Since 2006, France, Lithuania and Poland have changed their policies in the field. However, 3 countries (France, Greece and Ireland) state that they are planning to change their existing policies.

Although 22 countries have national policies for self-sufficiency of blood and blood components, only 13 of them seem in fact to have defined the concept of self-sufficiency (Austria, Bulgaria, Czech Republic, Cyprus, France, Hungary, Italy, Malta, Portugal, Romania, Spain, Sweden and Croatia).

In addition, France, Greece, Luxembourg, Malta, Slovakia and Norway report having bilateral or other forms of agreements/collaboration structures to ensure appropriate supply of blood and blood components at a national level.

3. SUMMARY AND CONCLUDING REMARKS

This report shows that Member States overall comply with Article 20(1) of Directive 2002/98/EC, requiring Member States to take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensure that blood and blood components are in so far as possible provided from such donation.

Largely in line with the findings of the first report on voluntary and unpaid blood donation (issued 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid blood donation are well established across the EU. All but one of the 29 reporting countries have such provisions in place.

Most reporting countries have some form of incentive structures for blood donors, such as refreshments, small token and reimbursement of travel costs. Several countries also offer blood donors employed in the public sector time off work. The study indicates that there are no major differences in incentives for whole blood donors and apheresis (plasma, platelets…) donors.

27 out of the 29 reporting countries have undertaken some form of measures to promote voluntary and unpaid blood donation, such as awareness raising and information campaigns.

Concerning collection and supply of blood and blood components, the report shows that collectors/suppliers of whole blood and plasma are predominately public in the EU, Norway and Croatia. About half of the reporting countries have the capacity for plasma fractionation. In these countries, actors in the field of plasma fractionation are mainly private (71%). With regards to supply, the Competent Authorities for blood and blood components report relatively limited shortages of blood and blood components, ranging from around 14% (for whole blood) to 0% for white blood cells. About 75% of the countries have policies in place to contain or ensure the effective clinical use of blood, as well as to promote self-sufficiency of blood and blood components.

Based on the findings of the report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's mandate is limited to quality and safety of blood and blood components.