The EU VUD Report and Its Impact

BY KARL PETROVSKY, PPTA SENIOR MANAGER, HEALTH POLICY

On April 26, 2016, the European Commission Directorate General Health-B4 Unit published the Commission Staff Working Document on the implementation of the principle of voluntary and unpaid donation (VUD) for human blood and blood components (the VUD Report). This VUD Report summarizes the results of a questionnaire survey on the implementation of the VUD principle, which was conducted in 2014 and sent to European Union (EU) Member States (MSs). The two preceding Reports were issued by the Commission in 2006 and 2011.

SCOPE OF THE VUD REPORT
The Report aims to map the implementation of VUD regarding blood and blood components in the EU. It mainly focuses on practices regarding donors and collectors, as well as provisions and policies related to VUD. It addresses the organization of collection and supply of blood, blood components, plasma derivatives, and how sufficient supply can be ensured through VUD.

MAIN FINDINGS AND CONCLUSIONS
With this Report, the Commission accomplished a substantial amount of in-depth ongoing work. The Report constitutes important progress compared to previous Reports as it is more complete.

The Report covers EU definitions of important terms that did not exist before, such as: compensation (with a rather positive tone), incentives (negative for DG Health, since it implies financial gain), national self-sufficiency (fulfilling needs from within a population), national sufficiency (fulfilling needs from within country and supranational cooperation), and shortage. The Report, however, expressly mentions that the definitions serve “for the purpose of this survey only.” This said, the definitions certainly reflect the thinking of the Commission and would need to be taken into consideration in future endeavors to possibly revise the EU Blood Directive.
VUD of blood and blood components is recognized in all EU MSs but differently enforced. Twenty-five EU MSs (and Norway) consider VUD as “mandatory” but mandatory is interpreted differently, sometimes as “encourage.” Seventeen EU MSs define penalties for infringement of their legislative provisions on VUD, however, none has ever been imposed.

Generally, the Report acknowledges the existence of a variety of compensation and incentive practices across the EU MSs:
• Around nine EU MSs have plans in place, referring to the strict term of “compensation,” linked to loss of earnings or inconveniences. The highest maximum values reported in the Report on compensation practices “lie between 25–30 euros (AT, CZ, DE, LV, RO).”
• Time off from work for public and private sector employees is offered in about half of the EU MSs; Greece and Bulgaria offer two days off, with Bulgaria offering this for employees in both the public and private sector, including for plasma donation.

However, not all of the existing practices are included, such as the tax deduction provisions for plasma donors (in the Czech Republic), which were mentioned in the previous Report and are still in place, but are not mentioned in the current Report.

Trans-border donation appears as a new item in this Report; this donation practice is confirmed by 11 EU MSs (amongst them “donor recipient” countries and “donor traveling” countries); 16 EU MSs have policies against trans-border donations. The Commission considers it as an individual practice.

Regarding the term “self-sufficiency,” the Commission set up two concepts: “national self-sufficiency” and “national sufficiency,” whereas the latter seems to be the broader concept and also includes the regional (EU) and international cooperation element to fulfill national needs. In doing so, the Commission seems to transform its concept of “community self-sufficiency” (in the recitals of Directive 2002/98/EC) into the “national sufficiency” concept, which includes regional and international cooperation. The newly used term of ‘sufficiency’ is an opportunity to look at sufficiency, or—over time—maybe better availability, as linked to regional (EU) and international cooperation outside the EU, so potentially including U.S. imports.

Donor pool aging and new epidemiological outbreaks, are cited as reasons for probable, occasional future shortages. Both elements are factors that have not been mentioned in the previous Reports nor in the Blood Directive.

The Commission is not taking a position on whether “ethics” play a role or not for VUD; the word “ethics” simply is not used.

Finally, the Commission is not drawing specific conclusions in this Report. However, from a general viewpoint, the Commission sees the need to start an Evaluation process on the functioning of the Blood Directive 2002/98/EC.

REGARDING NEW DEFINITIONS
The Report acknowledges that Directive 2002/98 (in recital 23) takes account of the definition of the Council of Europe for what is considered voluntary and non-remunerated donation, but notes the lack of definitions of the terms compensation, incentive, sufficiency, or shortage. This is why the Commission provides the following new definitions:
• Compensation: reparation strictly limited to making good the expenses and inconveniences related to the donation;
• Incentive: inducement/stimulus for donation with a view to seeking financial gain or comparable advantage;
• National self-sufficiency: fulfilling the needs of human blood, blood components, and plasma derivatives for medical application of the resident population by accessing resources from within the country’s population;
• National sufficiency: fulfilling the needs of blood, blood components, and plasma derivatives for medical application of the resident population by accessing resources from within the country and through regional/international cooperation;
• Shortage: a relative deficiency in the supply with blood, blood components, and plasma derivatives for medical application, which requires creation of waiting lists or makes a certain therapy temporarily unavailable at national level.

VOLUNTARY AND UNPAID DONATIONS
Overall, the Commission admits that these practices vary from one EU MS to another and there may also be different practices within a single country. The following types of practices are extracted from a figure in the Report, which the Commission identifies in three categories:

CATEGORY ONE
• Refreshments
• Food voucher(s)
• Small tokens, such as pins, pens, towels, t-shirts, and mugs
• Free physical check-up (beyond what is required for the donations)
• Free or reimbursement of medical costs (e.g. additional medication, etc.)
• Reimbursement of costs linked to travel (to and from place of donation)

CATEGORY TWO
• Time off work - public sector
• Time off work - private sector
CATEGORY THREE
• Compensation linked to loss of earnings
• Compensation for the inconveniences related to donation
• Fixed sum of money, irrespective of actual costs, established at the national level
• Fixed sum of money, irrespective of actual costs, established by individual blood establishments

THE REPORT’S LANGUAGE ON MAXIMUM VALUE PER DONATION
Figure 1 of the Report mentions a maximum value in euros for donation” regarding all practices vis-a-vis donors except for category two “Time off work - public and private sector”; the only criterion mentioned for this category is days/donation.”1 For category one: The “reported maximum values of refreshments and small tokens range between 1–10 euros, whereas for food vouchers (in six EU MSs) the value ranges between 1.4 euros (Latvia) and 15 euros (Romania)”. For category three: the “VUD Report mentions as “maximum values reported per donation the range between EUR 25–30 euros.”2 In Bulgaria and Czech Republic, the maximum values are defined as a percentage of the national minimum wage.”3 Overall, the report states that “the reported monetary reimbursement or compensation of more than one type should not be added.”4 Almost half of the EU MSs appear to have guiding principles regarding compensation to donors. However, overlaps exist between categories one and three since both categories imply financial elements, and obviously, category two also represents a financial value.

SELF-SUFFICIENCY
Almost all EU MSs (except Austria, Cyprus, and Finland) and Norway are reported to have policies in place to achieve self-sufficiency and/or sufficiency of blood and blood derivatives. In order to achieve (self-) sufficiency, EU MS policies aim either at increasing the supply via VUD, or through export restrictions. It is worthwhile to note that, according to the Report, only four EU MSs and Norway launched projects to increase apheresis donation.

SUMMARY
The Report constitutes an important progress compared to previous Reports, as it is much more complete and covers EU definitions of important terms, which did not exist before. These definitions would need to be taken into account in forthcoming processes to improve the legal framework around plasma collection. Generally, the Report acknowledges the existence of a variety of compensation and incentive practices across the EU MSs. Compensation is seen by the Commission as rather positive, whilst incentives are rated as negative, since they imply, for the Commission, financial gain.

Finally, the Commission is not drawing specific conclusions in this Report. However, from a general viewpoint, the Commission sees the need to start an evaluation process on the whole functioning of EU Blood Directive 2002/98. PPTA is ready to participate in such evaluation consultation as one of the key stakeholders.

References:
2 Ibid. page 10.
3 Ibid. page 10.
4 Ibid. page 8.