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LETTER

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Letter to the Editor – Response to 'How expanding voluntary non-remunerated blood donations would benefit patients, donors and healthcare systems?' – F. Rossi, R. Perry, J. de Wit,T. Evers & G. Folléa, *Vox Sanguinis* DOI: 10.1111/j.1423-0410.2011.01495.x

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Rossi *et al.* [1] assert that our [2] perception of IVIG usage as an indicator of plasma needs is based on North American IVIG usage and that this level of usage is not based on evidence. The highest users of IVIG per capita include Australia, Canada and Sweden [3], countries with social market heath systems delivering IVIG on a strict evidence basis. An analysis of the sole indications reimbursed by Australian authorities [4] shows that these are assigned a Level 1 classification in the Evidence Based Medicine hierarchy. The guidelines overseeing the usage of Ig in these high usage countries are similar to those in the low usage countries listed by Rossi *et al.* [1], but reported disease prevalence as indicated by registries of the European Society for Immunodeficiency [5] varies considerably. This is because of under-diagnosis of the relevant medical conditions such as primary immune deficiency (PID), which demonstrate a uniform prevalence where they are studied, not the result of optimal use. This is an issue of considerable anxiety to patient groups, in, for example, Germany [6], which is held by Rossi *et al.* [1] as an exemplar of equivalent clinical outcomes with low consumption.

Rossi *et al.*'s [1] limitation of Europe to the pre-expansion countries of the former EU excludes 20% of the Community's population of 500 million people from consideration and treatment and runs counter to the relevant Commission Directive, specifying self-sufficiency for the whole Community [7]. Their assertion that 4.5 million litres of plasma would provide product sufficiency for this population implies with that the maximum yield of 4.5 g of Ig per litre of plasma currently available, the population of the EU can expect a supply level of 36 g of Ig per 1000 population. Patients and treaters should be concerned at this minimal level, totally inadequate for the treatment of all evidence-based indications for Ig, being proposed by an organization charged with providing patients with blood products. This estimate includes the 2500 tonnes of apheresis plasma from compensated donors in Germany, Austria and the Czech Republic, needed for the supply of essential products globally.

Rossi *et al.* [1] asset that a pluralistic collection system would affect whole blood collection. The three countries in the EU allowing such a system – Germany, Austria and the Czech Republic – average 55.9 blood collections per thousand population, which is well above countries, such as France and the Netherlands, which do not allow a pluralistic system. In the Czech Republic, regions of high blood collection also show parallel high-compensated plasma collection [8].There is simply no evidence to support the assertion of Rossi *et al.* [1] or their cited authorities. Rossi *et al.* [1] conclude by stating that a shortage of pdMPs is not established. Patients and treaters, suffering from a lack of supply and choice as a result of restricted access to products, might have a different view. In a world, where 70% of haemophiliacs and similar proportions of patients with PID and other rare plasma protein deficiencies remain undiagnosed and untreated, it behooves all those engaged in the supply of plasma protein therapies to increase, rather than to restrict, access and supply.

References

1 Rossi F, Perry R, de WitJ, *et al.* How expanding voluntary non-remunerated blood donations would benefit patients, donors and healthcare systems? *Vox Sang* 2011; **101**:176–177
2 Farrugia A, Penrod J, Bult JM: Payment, compensation and replacement – the ethics and motivation of blood and plasma donation. *Vox Sang* 2010; **99**:202–211
3 Robert P. Worldwide supply and demand of plasma and plasma-derived medicines. *Iran J Blood and Cancer* 2011; **3**:111–120. On http://www.ijbc.ir/browse.php?a_code=A-10-2-196&tslc_lang=en&tsid=1&tftxt=1. Accessed on 6 July 2011
4 Australian National Blood Authority. Criteria for the clinical use of intravenous immunoglobulin in Australia. On http://www.nba.gov.au/ivig/pdf/criteria.pdf. Accessed on 6 July 2011
5 Gathmann B, Grimbacher B, Beauté J, *et al.*: The European internet-based patient and research database for primary immunodeficiencies: results 2006–2008. *Clin Exp Immunol* 2009; **157**(Suppl. 1):3–11
6 German Patient Organisation for Primary Immunodeficiencies. Presentation at the international congress of the international patient organisation for primary immunedeficiencies, 2010. On http://www.ipopi.org/uploads/media/PastEvents/presentations/Deutsche%20Selbsthilfe%20Angeborene%20Immundefekte%20e.V.%20% 28dsai%29.pdf. Accessed on 6 July 2011
7 European Commission. DIRECTIVE 2002/98/EC of the European Parliament and of the Council. On http://www.google.com/url?

sa=t&tsource=web&tcd=1&tved=0CBcQFjAA&turl=http%3A%2F%2Feur-lex.europa.eu%2FLexUriServ%2FLexUriServ.do%3Furi%3DOJ%3AL%3A2003%3A033%3A0030%3A0040%3AEN%3APDF&tei=ussTTqPFG5DPmAXGjsT4Dw&tusg=AFQjCNG4NxWfZ3tA65JexkKtrpdhxm5c7w. Accessed on 7 July 2011

8 Institute of Health Information and Statistics of the Czech Republic. Activity of health care institutions in the section of transfusion service in the Czech Republic, 2009. On http://www.uzis.cz/system/files/39_09.pdf. Accessed on 6 July 2011

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