UK donor plasma could have an immediate beneficial effect on the availability of plasma derived medicinal products in Europe

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Dear Editor

We welcome the news that the European Medicines Agency (EMA) will, in 2023, review the *Committee for Medicinal Products for Human Use (CHMP) Position Statement on CJD and plasma-derived and urine derived medicinal products (EMA/CHMP/BWP/303353/2010)* [1]. This is in response to stakeholder requests that highlight the increased risk to immunoglobulin supply and the diminishing risk of variant Creutzfeldt-Jakob Disease (vCJD). We have recently reviewed the safety profile of United Kingdom (UK) plasma with respect to vCJD [2] and have concluded that it is a safe starting material for the manufacture of Plasma Derived Medicinal Products (PDMPs).

From the perspective of European Member States, the UK's return to plasma fractionation will have two key benefits. First, by becoming more self-sufficient, the UK will source less of its immunoglobulin requirement from the international market. Given the significant volume of PDMPs already used in the UK, accepting plasma from UK donors is perhaps the biggest single action that any actor in Europe could take to immediately increase total plasma for medicines collection in Europe. This would reduce dependency on importation, which is primarily from the United States of America (US) where plasma has recently been designated as a strategic resource, meaning that exports may be restricted [3]. We have previously reported that Europe (including the UK) requires 64 tons of immunoglobulin per annum for up to 350,000 patients [2] and demand is rising <6% per year [4]. Secondly, the acceptance of donors that have previously resided in the UK will also have beneficial effects in European countries where many currently deferred donors will become eligible to donate whole blood and plasma again.

Recent changes in donor acceptance criteria in some jurisdictions have led to immediate benefits in the supply of blood and plasma. For example, Australia lifted its UK geographical deferral on 25 July 2022 and data from Australian Red Cross Lifeblood reveals that in the six-month period after removing the deferral, there were over 32,000 newly-eligible UK donors that successfully gave just under 68,000 donations[5].

Using migration data from the UK Home Office we estimate that of the 12.8 million people that have emigrated since 1980, 7.7 million were in the UK at some point

between 1980 and 1996 [6]. Of those we estimate that 4.3 million have not since returned to the UK and of which 1 million are in either the USA or Australia (where they are now eligible to donate) and 1.8 million are in Europe. If the reviewed CHMP position statement were to allow these people to donate again, there would be an immediate benefit to the European plasma supply. Based on the proportion of the UK population that donate blood (1.53%, [7, 8]) Europe could immediately benefit from 26,000 donors who, if they donate at the average UK rate of 1.7 times per year (rather than the four times per year seen in newly-eligible donors in Australia) could contribute at least 12,000 litres of recovered plasma per year. If 4 % become plasma donors and donate 600 mL five times per year, this could add a further 3,000 litres per year of source plasma [9].

It is vital to have an updated Europe-wide position to strengthen total European plasma supply, as well as to clear the regulatory path for the many EU based fractionators that have expressed enthusiasm for working with UK plasma. From our conversations with the industry, it is clear that the current recommendations from both the EMA [10] and the European Centre for Disease Prevention and Control [11], for individual countries to conduct their own risk assessments, is unhelpful. To avoid a potentially large duplication of effort, many countries are awaiting a central recommendation from the EMA, and this guidance is needed to provide certainty to EU member states that plasma fractionators could obtain the necessary manufacturing licence to work with UK plasma. In the interim, given the challenge of operating two separate donation and processing streams, many blood services simply defer ‘UK donors’ from donation. Acceptance of UK donors would therefore enable countries to collect whole blood for the preparation of labile components and to recover plasma for fractionation from these donations. This would ensure best use of all donations and maximum benefit to patients across Europe.

The UK is currently collecting around 300,000 litres of recovered plasma per year and hopes to also direct a further 40,000 litres of cryo-depleted plasma to fractionation. Together with the contribution from former UK residents in Europe, there is the potential for the immediate availability of 355,000 litres per year of plasma to be available for fractionation. This is equivalent to the output of 18 mature and high-performing plasmapheresis centres and would relieve a significant amount of pressure on the supply of life-saving PDMPs to patients in Europe.

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