United Kingdom Plasma Action

"Best Husbandry of the Donors' Gifts. Best Care for Patients"

Short-Form Memorandum

on

The urgent need to secure more, and more reliable, supplies of Immunoglobulin (Ig)
and other plasma-derived pharmaceutical products for patients in need,
in the face of growing global shortages of these vital medicines,
via
The discontinuation of the current ban on the pharmaceutical use of
UK donors' plasma and its re-acceptance for medicines manufacture.

12.11.2019

Issued by UK Plasma Action, in Association with

UK PIN
Advancing Care in Primary Immunodeficiency

British Society for immunology

PID UK
Supporting families affected by primary immunodeficiencies
Part of Genetic Disorders UK

Immunology & Allergy Nurse Group

1 **UK Plasma Action** (UKPA)

1.1. UKPA is an independent not-for-profit organisation founded in June 2019 in response to three important national issues, together seen as a significant and rising threat to UK healthcare services and to the health and welfare of the patients they exist to serve. The issues of concern to the teams at UKPA, BSI, IANG, PID UK, UKPIN and those they represent are:

a) a growing global shortage of human plasma, causing increasing shortages of immunoglobulin (Ig) and other plasma products upon which thousands of patients depend for their quality of life and often for life itself;

b) an increasing global dependency on the USA for supplies of human plasma products. These are classified by the WHO as Essential Medicines in all countries, but US exports currently account for some 70% of global supplies; causing strategic vulnerability for the UK and other countries who are entirely dependent on imports; and

c) the currently unrealised potential of some 300,000 litres per annum of UK blood donor plasma, which could make a significant contribution to the sufficiency and security of supply of Ig and other medicines, but is not currently available for this use, due to the UK ban introduced in 1998 as a precaution against Variant Creutzfeld Jakob Disease (vCJD).

2 **UK Donors' Plasma - 2019**

2.1 Though the UK's ban on the pharmaceutical use of recovered plasma has always had unwelcome consequences, in overall cost and plasma product availability, it has been felt justified for safety reasons. Twenty years on however the balance of risks in this area can be seen to have shifted significantly. A parallel precautionary ban on certain uses of fresh plasma, also instituted in 1998, was recently reviewed by the UK's expert committee on the Safety of Blood, Tissues and Organs (SaBTO). They found that the risks were now lower than previously thought, that the costs and drawbacks of maintaining the old policy were relatively too great and the policy should therefore be changed. The old restrictions on the use of UK fresh plasma were therefore lifted in September 2019; but there has as yet been no equivalent up-date of plasma product policy.

2.2 Because of the potential relevance of the SaBTO work to the issues highlighted above, the UKPA team has considered and investigated the possibility that it might be built upon, in a follow-up study into the risks attached both to the use and to the non-use of UK recovered plasma. This is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA) and its expert advisory committee, the Commission on Human Medicines (CHM) and falls outside the SaBTO remit.

2.3 After wide consultation with practicing clinicians, haematologists and other specialists in relevant fields, including UKPA's Principal Scientific Adviser, Professor Richard Knight (Centre for Clinical Brain Sciences, Edinburgh University), the UKPA team feels it appropriate to respectfully suggest that the MHRA/CHM should now take up the subject, building on SaBTO's findings and on the evidence and experience of the last 20 years, in the UK, France and elsewhere.

3 The Need for Action

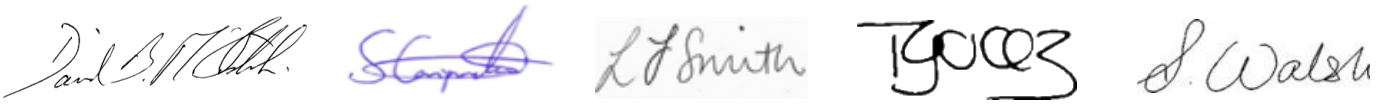
3.1 Bearing in mind the current and growing risks of shortages in supply of vital plasma products, especially immunoglobulin, the UKPA team believes that a risk re-assessment is an important and urgent priority, on the basis of three preliminary conclusions, set out here and expanded upon in a supporting UKPA Memorandum, available on request. These are:

a) that SaBTO's recommendations, with which the UK government has agreed in lifting the old restrictions on the use of fresh plasma, are based on reasoning much of which is also relevant to the recovered donor plasma position;

b) that this, together with other supporting evidence and the changed situation with regard to risks in the area of imported product supply sufficiency and security, suggests the urgent need for a re-assessment of the relevant balance of risks, re-visiting the advisability or otherwise of excluding UK donors' plasma from the medicines supply chain; and

c) that if such a review were to lead to the lifting of the ban on UK donors' recovered plasma that would be a highly desirable outcome – one that would deliver significant benefits for patients, for clinicians, for blood donors and for the NHS as a whole; in terms of safety, patient care, national security of medical supplies and also significant savings in cost.

3.2 Therefore, the UKPA team, the BSI, IANG, UKPIN, our patient representative partners PIDUK, and the many patients, clinicians and donors for whom we speak, urge the UK Department of Health and Social Care, the MHRA and the CHM to please act promptly to initiate the required review and to implement the resulting recommendations without delay.



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