

1st November, 2018



World-wide plasma shortage

You may have become aware that there is a world-wide plasma shortage and be wondering if this will have any impact on your treatment and if so, why. This document will try to explain this to you.

What is plasma?

Plasma is a constituent of blood. Amongst other things, it contains many proteins essential for keeping our bodies free from infection. Plasma can be separated from other parts of the blood by special machines. The red component of blood is taken away, leaving the golden yellow plasma. Plasma makes up about 55% of the total blood we all have in our bodies. For those of us living with an Antibody Deficiency, the important parts of the plasma are the immunoglobulins.

How are Immunoglobulin Replacement Products made?

Immunoglobulins are removed from the plasma, then cleaned and made into a safe and stable product for us to use. This YouTube video may be helpful:

<https://youtu.be/nzs7N8AnA-4>

Where does the Plasma come from?

Plasma comes from people who donate it, in a similar way in which blood is donated. You may find these YouTube videos helpful:

<https://you.be/Qf6a-pyKXDE>

<https://youtu.be/y4TsBv7aCpY> and <https://youtu.be/nkXzG1k2DC1>

Where can people donate plasma in the UK?

Currently, plasma cannot be donated in the UK. This is because the Government is concerned that following the outbreak in the 1990's, there may still be a remote risk that variant Creutzfeldt-Jakob disease (vCJD) could be present in a dormant state within the UK population and that this could possibly be transmitted to recipients of UK donated plasma. The situation of being able to resume using UK donated plasma is still under critical review, making full use of *new* information and using more recently developed diagnostic tools. However, at this time the decision of whether to resume using UK donated plasma - or not, has yet to be taken.

What does this mean for Primary Immune Deficient Patients (PID) in the UK?

It means that all the plasma used to make the replacement immunoglobulin therapy (IgG) that some PID patients need to stay well, is sourced from donors in other countries. Most donated plasma comes from the USA. People who donate plasma are very rigorously checked to ensure that they are well, firstly so that they do not pass on any illness to those of us receiving a plasma product and secondly, to ensure that giving plasma will not make the donor unwell. Since the UK does not provide any plasma to be made into immunoglobulin, our National Health Services in England, Scotland, Wales and Northern Ireland have to buy all the IgG we need from pharmaceutical companies and these pharmaceutical companies have to sell their product all over the world. Because of this, the price that has to be paid for IgG by our NHS' is affected by the prices throughout the world for IgG, in just the same way that prices of thousands of other items bought from abroad are affected. Most of us are aware of the way in which the world prices for oil, coffee and tea affect how much we have to pay in the UK, the price for immunoglobulin changes in exactly the same way.

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Why is there a World Plasma Shortage and how does this affect PID patients?

As more and more countries across the world have realised that plasma products can keep patients alive, the demand for plasma has suddenly increased. In a way this is a good thing, since it means that PID patients in other parts of the world are now able to stay alive as IgG is made available to them by their governments. However, this increase in demand for plasma products happened very quickly and caught everyone by surprise. It takes up to 18 months from the time a person donates their plasma until the immunoglobulin made from it is ready to be given to a PID patient. All the companies throughout the world who make immunoglobulin products, are taking steps to ensure that they can produce as much as is needed to meet current and anticipated future world demand, but this will take at least a year to result in a higher production level of IgG.

What are the NHS' in the four UK Home Nations doing about this?

IgG can be used for people with illnesses other than PID. The UK Government has a document called **Clinical Guidelines for Immunoglobulin Use** (second edition) and this can be found at:

<https://www.gov.uk/government/publications/clinical-guidelines-for-immunoglobulin-use-second-edition-update>

This document identifies what conditions may be suitable for IgG replacement therapy. PID patients are identified as having the highest need for IgG since, for this cohort of patients, it is life-sustaining. Currently, our NHS' services are working very hard with all of the pharmaceutical companies to ensure that there is always enough IgG for PID patients. However, as we mentioned in our letter to you dated 1 May 2018, this may mean that some PID patients have to switch IgG product, or switch to an IgG product which is delivered via a different method to the one currently used

Will there be enough IgG for all PID patients?

There will be enough IgG for all PID patients, but this will mean that patient cohorts who currently receive IgG for other illnesses that are not Immune Deficiencies, may have to stop having IgG therapy. If this happens, their clinicians will work with the NHS' to ensure that other appropriate treatments are available to them.

What is UKPIPS doing about this?

UKPIPS believes it is essential that the Department of Health provides a ring-fenced "Immunoglobulin Fund" to all the UK NHS services in the four home nations and that this fund should be sufficiently high to enable IgG to be purchased at World prices. We have already stated this to the Department of Health and will confirm that we expect that this ring-fenced fund will take account of the increase in demand every year, as new patients are diagnosed with antibody deficiency. We have also requested the UK Government to carry out a study with pharmaceutical partners, to evaluate the safety of collecting plasma from the general public in the UK. Once such a study has been undertaken, we will know whether UK plasma can be used to safely make IgG for UK patients without exposing them to any risk connected with variant CJD. We trust that the UK Government will prove willing to approve this study.

Should PID patients be worried that they may not be able to have IgG infusions because of the world-wide shortage of Plasma?

PID patients should **not** be worried that they will be unable to have IgG infusions. The NHS', the pharmaceutical companies and all of our Clinical Immunologists are working together to make sure that IgG infusions are available to **all** PID patients that need them.

What can I do now?

If you would like more information on how UKPIPS is working with the UK Government and the NHS, please contact us at admin@ukpips.org.uk or by post to: UKPIPS, De Montfort House, 7e Enterprise Way, Vale Business Park, Evesham, Worcs. WR11 1GS or by telephone 01386 421228. There is a confidential Voicemail, which runs continuously.

If you have any concerns about your own medical care you should contact your Clinical Immunology Team.