Annex B

FUTURE SUPPLY OF PLASMA DERIVED PRODUCTS TO THE NHS

Introduction

1. The remit for the BPL review requires consideration of "how the NHS in England and Wales can be provided by BPL with a secure supply of sufficient, competitively priced product in the event of global shortage". This is a key criterion for the Department in judging the acceptability of any option for the future of BPL. Furthermore, any restrictions we wish to place on a future BPL partner around security of supply will at least partially determine structural options and may impact on the value to be achieved from the reconfiguration of BPL. It is therefore essential that we have a clear and common understanding about what "security of supply" really means and the extent to which it is achievable in practice.

2. Security of supply is much more of an issue for blood products than for pharmaceutical products in general. As biologicals, the production of plasma-derived blood products is subject to increasingly rigorous regulation by the MCA and the US Food and Drugs Administration (FDA). Both authorities have the power to shut down plants if they fall seriously short of the required standards, and recent shut-downs in the US have led to world-wide shortages of some products.

3. This paper is therefore structured to focus on two areas concerning security of supply:

- the likely future demand for plasma derived products from the UK;
- the mechanisms by which the level of security required could be provided in the future.

The Likely Future Demand for Plasma Products from the UK

5. BPL has produced a paper on likely future demand for plasma based products (attached). This assumes that:

- sales of plasma-derived Factor 8 & 9 will decline to very low levels in the UK due to the increasing use of recombinant products for the treatment of haemophilia.;
- world wide surpluses of albumin, the use of which is declining, means that it unlikely that the UK would ever run short of this product.

The only products that could suffer from problems of supply in the future are therefore identified as immunoglobulins and some more rarely used clotting factors such as Factor 7 and Factor 11.

BPL supplies three types of immunoglobulin:

- ***Intravenous immunoglobulin***; critically used by people with immune deficiency but increasingly for a variety of other uses. BPL is currently the market leader (with about 50% of the supply market) for this product in the UK. As such BPL is capable of providing enough Immunoglobulin to meet the needs of all immune deficient patients in the UK who account for around 25-33% of the total current demand.

- ***Anti-D immunoglobulin***; used to treat approx 90,000 pregnant Rh negative mothers per year. BPL is currently the dominant supplier to NHS and private hospitals for this essential use.

- ***Specific Immunoglobulins***; BPL directly supplies the Public Health Laboratory Service (PHLS) with Hepatitis B, Varicella Zoster and Rabies Immunoglobulin and the Ministry of Defence (MoD) with Rabies Immunoglobulin. BPL is the sole licensed supplier of Hepatitis B, Varicella Zoster and Rabies Immunoglobulin to the UK (apart from PFC who supply small quantities of Hepatitis B and Varicella Zoster in Scotland and N.Ireland) and their supply to the PHLS and MoD is therefore sensitive.

6. It needs to be ensured that all these types of immunoglobulin, and the more rarely used clotting factors, continue to be available to essential UK users under any new ownership arrangement for BPL. It is proposed that the future needs of PHLS and MoD for specific immunoglobulins should be met through contracts between these bodies and BPL. However, we need to ensure that sufficient supplies of these products are also available to NHS hospitals.

How Security of Supply could be Provided in the Future

7. This section considers how security of supply can be ensured for Immunoglobulin in the future under new ownership arrangements. This is considered in two parts:

- Firstly, defining what security of supply for plasma products means

- Secondly, outlining the options for providing security of supply in the future.

Defining Security of Supply for Plasma Products

8. Examining the nature of plasma product supply reveals that there are two key resource constraints involved:

- ***plasma supply to the UK***; the UK is dependent on other countries for the supply of plasma since the ban on the use of UK plasma. At the moment BPL has two year rolling contracts with plasma suppliers in the USA which are renewable annually; meaning that BPL has at least one year's guaranteed plasma supply at any time. In addition, BPL is currently building up a further 60 day stock within the plant. It should be stressed that BPL has to work very hard to obtain sufficient supplies of plasma from the US and that there may be further demand for US

plasma if other European countries, notably France, switch to imported plasma. There is therefore no long-term security of supply of plasma [as is now the case];

- ***fractionating capacity***; a licensed fractionating plant with sufficient capacity is required in order to break the plasma into the proteins required. Currently access to such capacity is assured in the UK by the public sector owning BPL.

9. Both of these constraints will need to be addressed when considering future ownership scenarios for BPL and the options for doing this are presented below.

Options for Providing Security of Supply in the future

10. Presented below are the options that address the two key resource constraints for security of supply.

Options for Addressing Future Plasma Supply to the UK

11. As highlighted above, under current arrangements BPL is always contracted for at least one year's supply of plasma at any time. This means that any short term changes in the plasma market (such as further countries being unable to use their plasma supply because of the occurrence of vCJD) are unlikely to immediately affect plasma supply to the UK. (Unless US plasma becomes unusable or the US government takes some emergency action to ensure all plasma is directed to home use.) However, in the longer term, difficulties in plasma supply will inevitably push the price of plasma up.

12. Any changes in plasma supply, such as price increases, are therefore unavoidable under any ownership option including retention in the public sector. But in order to ensure complete replication of current security of supply it is proposed that under new ownership arrangements BPL must be required to contract with US plasma suppliers using contract lengths that are no shorter.

Options for Ensuring Sufficient Fractionation Capability Exists

13. In order to turn plasma into products access is required to an appropriately licensed fractionating plant with sufficient capacity. The UK currently assures such access by retaining ownership (which brings other risks). This access could be protected under future ownership scenarios by three options outlined below:

- ***Requiring pre-emptive supply to the UK market***; under this option the new owners of BPL would be required to give assurances of pre-emptive supply to the UK's immunoglobulin needs (this would need definition but is likely to be based on immune deficients, Anti-D, PHLS and MOD requirements.) Such commitments from the new BPL are unlikely to be particularly onerous in volume terms. BPL's current export contracts, which recognise that in times of supply difficulty the UK market will always gain preferential supply, provide a precedent for such an arrangement.

- ***Corporate governance of the New BPL***; the Public Sector can affect the future preferential supply to the NHS by ensuring that it has such powers via the

governance arrangements of the new organisation, this might be in the form of the public sector:

- Maintaining a majority share of the new BPL
- Holding a golden share in the new BPL
- Designing a governance structure which allows it sufficient influence on future decisions about pre-emptive supply (eg a majority of board seats)

- ***Use of PFC as a back up***; PFC (the Scottish fractionator) has only limited fractionating capacity - 100 – 130 tonnes per annum. They make all immunoglobulin types except rabies, and could perhaps supply limited quantities of product to hospitals in England & Wales in an emergency. However, they could not make enough immunoglobulin for immune deficient patients in the UK.

14. In summary, it can be seen that by applying one or more of the options above it is possible to assure security of supply without retaining ownership of the fractionating capacity. It should of course be recognised that each of these different options do however bring some additional cost to the future arrangements for BPL.

Conclusion

15. Overall it can be seen above that ownership of the fractionator is not the only method for ensuring security of supply. By careful application of the options above it will be possible to provide security of supply equivalent to that currently enjoyed. The proposed options for doing this are outlined below.

16. As indicated above the security of plasma supply will be equal under any ownership option as long as the new BPL is required to engage in contracts of the same length as those currently held by BPL.

17. In order to provide current levels of security of fractionating capacity it is proposed that a pre-emptive supply agreement for the UK's minimal immunoglobulin requirements (which need to be defined) be included as the foundation of any future ownership option. This should be further re-inforced, if possible, by an appropriate 'golden share' governance structure that allows the public sector some control over the new BPL. In addition, PFC may be able to provide some limited stop-gap provision.

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