EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Meeting between NHSBT (NHS Blood and Transplant, UK) with DG SANTE B4

19 February 2016

Summary Minutes

Participants:

NHSBT: Lorna Williamson, Sheila MacLennan, Ian Bateman

NHS European Office: Elisabetta Zanon, Sarah Collen

EBA (European Blood Alliance): Kari Aranko

DG SANTE (Unit B4): Dominik Schnichels, Stefaan Van der Spiegel, Deirdre Fehily

NHSBT had requested the meeting with DG SANTE to update them on their experience of implementing the blood, tissues and cells and organ legislation and to discuss current developments in the field. They had invited the European Blood Alliance (EBA), of which they are a member, to be present at the meeting. During the preliminary introductions of participants, the role of NHSBT in blood, organs, tissues and cells in England was summarised. The participants also represented the Joint Professional Advisory Committee (JPAC) of the 4 UK blood services.

1. Mr Schnichels opened the discussions by describing the recent reorganisation of DG-SANTE (effective February 1st 2016) whereby the SoHO team is now in the same unit as two other teams, one working on Health Technology Assessment and one on aspects of pharmaceuticals including clinical trials, GMP and plasma derived medicinal products.

2. SANTE-B4 informed the participants that reports on the implementation of the blood and tissues & cells directives are about to be published (with annexes that provide the results of the surveys conducted with Member States on implementation and on the principle of voluntary and unpaid donation (VUD)). The conclusion of the exercise was that an in-depth evaluation of the legislation might be needed – without pre-judging any potential follow up. The evaluation is beginning and is likely to take at least a year and will include public consultation and probably consultation with targeted stakeholders. It was confirmed that a shorter Implementation Report is under

development for the Organ directive but no evaluation is under consideration at this time for this, more recent, legislation.

3. It was noted that NHSBT had provided comments on Directive 2004/33/EC prior to the meeting. These had highlighted various technical issues associated with donor selection and testing which, in the view of NHSBT, require revision to be in line with epidemiological and technological changes since the directive was adopted. By way of example they underlined their concern about the requirement for single donor NAT testing for West Nile Virus. It was stated that this will have significant cost implications without increasing safety, as their mini-pool testing has been validated to achieve an acceptable risk level (as an example it was noted that the Dutch calculations for mini-pool testing are 1 likely transmission in 1,200 years). They recommended that in future such requirements be expressed in terms of sensitivity and risk rather than in terms of a particular testing method.

4. EBA had also provided SANTE-B4 with a statement concerning their views on the need to revise the blood directives. Their approach was rather to remove very specific technical requirements that are likely to change frequently (such as those discussed at point 3 above) and instead to cross reference guidance that is regularly updated, such as the EDQM guides. NHSBT representatives confirmed that they would also be very favourable to such an approach.

5. SANTE-B4 explained that there will be an amendment to Directive 2005/62/EC adopted soon that will clarify that the Good Practice Guidelines (GPG) to be followed (Article 2) should be the GPG jointly developed by the Commission and EDQM and published as a distinct section of the Council of Europe Guide to the preparation, use and quality assurance of blood components. This development was welcomed by all participants.

6. NHSBT raised the issue of the many innovative preparations that are now in routine use but for which the regulatory status is unclear – blood components that are 'not for transfusion'. They referred specifically to serum eye drops and to platelet gels. They highlighted the need for these preparations to be regulated appropriately. They considered that there is a risk that the lack of regulatory clarity of these very effective therapies might lead to 'over' regulation (e.g. classification as ATMP).

7. NHSBT representatives stressed the need to include requirements for demonstration of efficacy of blood components, tissues and cells that are processed in novel ways. They explained that there are many good clinical trials and patient follow up studies ongoing but this is not foreseen in the legislation and this approach might not be uniformly applied. They consider that an 'appropriate' level of demonstration of clinical safety and quality needs to be defined that is somewhere between the current requirements (no clinical demonstration required) and the requirements for demonstration of efficacy for medicines (compliance with clinical trials directive).

8. The need to strengthen the provisions for donor protection was stressed by NHSBT representatives who considered that the current legislation does not provide appropriate safeguards or donor vigilance reporting requirements.

9. NHSBT reported that they have invested very significantly (£2.7 million a year) in paying for consultant haematologists who work part time for their service and half time for large hospitals where they promote good clinical practice and, particularly, patient blood management (PBM). The use of red blood cells has fallen steadily over recent years. This is seen as a very positive trend for patients, although they stressed the need for good follow-up studies of patients who leave hospital with haemoglobin levels that are lower than would have been accepted in the past.

10. Despite this steadily decreasing trend in blood usage, and the fact that UK plasma cannot be used for fractionation because of vCJD risk, the price of blood has fallen every year since 2007. This has been achieved through huge reductions in capacity (now only 2 testing centres and 5 processing centres for England) and the introduction of 'lean management' processes. In the current economic climate it is likely that this trend will be seen throughout the EU.

11. On the topic of vigilance, they confirmed that the most serious and common adverse reactions and events continue to occur at the hospital level and are often associated with the wrong blood component being given to the wrong patient. A study in Oxford has shown very significant improvement through the use of barcoded wrist bands on patients but this approach has not so far been taken up generally.