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 Medtech Europe and DG SANTE B4

25 June 2018

Summary Minutes

Participants:

Medtech Europe: Kacper Olejniczak, Oliver Bisazza, Nigel Talboys (Terumo and Medtech Europe)

DG SANTE (Unit B4 Medical products: quality, safety, innovation): Anna Eva Ampelas, S. Van der Spiegel, D. Fehily, I. Pucinskaite-Kubik.

Medtech Europe[1] had requested the meeting with DG SANTE B4 as a follow-up to the Open Public Consultation (OPC) on the EU blood, tissues and cells legislation held during 2017. The OPC had been organised as one of the steps in an ongoing process of formal evaluation of that legislation. Medtech Europe indicated that their members had expressed interest in this consultation as relevant for the medical technology industry. Their objective was to understand better SANTE B4's current perspectives and the state of play. Medtech Europe had submitted to the OPC to express their views on shortcomings in the current legislation for blood and Terumo had submitted comments on both blood and tissues and cells.

1. Following the introduction of the participants, DG SANTE explained to the Medtech Europe representatives that the Commission is not currently working on a revision to any of the blood or tissue and cell Directives. The current initiative is limited to evaluating the existing legislation, with a view to establishing whether it achieved its original objectives and whether it is still fit for purpose. DG SANTE updated the stakeholders on progress with the evaluation. In general, the process is on schedule and the final report should be published by the end of 2018 or early in 2019.

2. The Medtech Europe representatives described the importance of the medical technology industry for the blood and tissue and cell sectors. Recent interruptions in device supply had

[1] MedTech Europe is the European trade association representing the medical technology industries. It is an alliance of European medical technology industry associations representing Diagnostics and Medical Devices manufacturers operating in Europe. It was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry.

illustrated that the continuity of supply of devices is a critical element for ensuring a continuity of supply of blood, tissues and cells. This has been evident both for diagnostics (e.g. kits for donor infectious disease markers) and for other devices, such as culture media for in vitro fertilisation (IVF) where supply interruptions in recent years have impacted on the continuity of the service. DG SANTE informed Medtech that it intends to co-ordinate with EDQM (Council of Europe), and with EU authorities, some work on continuity planning for the blood supply in the EU and that the involvement of the device industry would be important in this initiative. The stakeholders noted that in the United States, Terumo participates in an initiative that plans for blood supply crises and that is co-ordinated by the American Association of Blood Banks.

3. In that context, Medtech agreed to draw up a list of critical devices that they supply for blood collection, testing or processing and to provide it to DG SANTE. The list will include those devices that contribute to i) an uninterrupted supply of blood and blood components for transfusion and ii) an uninterrupted supply of plasma for the manufacture of plasma derived medicinal products.

4. The meeting discussed the significant changes that have taken place in relation to pathogen reduction technologies in the blood services in recent years. In many Member States, pathogen reduction steps during the processing of platelets is now routine and, in at least one (Belgium), it is required by national legislation. Some stakeholders have suggested that pathogen reduction, where feasible, should be mandated at the EU level. DG SANTE asked Medtech if they can provide information on the benefits and costs of pathogen reduction (e.g. for platelets) across the EU. Medtech also explained that having a test or technology included in legal requirements often facilitates reimbursement of the cost.

5. The participants discussed the procedures currently followed for the demonstration of clinical safety and efficacy following the introduction of a new blood processing technology and how the costs are met. Medtech observed that the current legal framework is restrictive in terms of allowing for uptake of innovative technologies, and that full clinical trials are not always feasible nor necessary.

6. Medtech explained that full clinical trials are very costly but sometimes are funded by individual governments e.g. the large trial funded by the Dutch government to evaluate the clinical effects of pathogen inactivation of platelets that included 567 transfused patients[2]. The organisation of such studies is often complicated by funding competition with studies on economically more interesting pharmaceutical products. Terumo has participated in many such clinical studies[3]. Clinical trials and observational studies can have a major impact on the cost of introducing new technologies in this sector.

7. The impact of a lack of full harmonisation of safety and quality requirements for blood, tissues and cells on the medical technology industry was discussed. In general, greater harmonisation of requirements is better for the industry as long as the requirements are set at a reasonable level.

[2] The Pathogen Reduction Evaluation and Predictive Analytical Rating Score (PREPAReS) trial https://bmjopen.bmj.com/content/6/1/e010156.full

[3] http://www.aabb.org/tm/eid/Documents/prt-clinical-trials-terumo.pdf

8. It was noted that the decreasing demand for red blood cell transfusions has resulted in over-capacity in some companies that manufacture and supply related devices, notably blood bags. The latter has caused a dramatic fall in the price of blood bags. A certain degree of consolidation of companies in this field has been seen that may be partially due to this factor. This overcapacity could also lead to an interest of (national) blood services providing blood components to hospitals in other Member States.

9. DG SANTE noted that Terumo had raised topics in their OPC submission relating to tissues and cells. In particular, they had pointed to inadequacies in the current legislation to address the development of highly automated procedures for collection and processing of cells. In addition, comments regarding the impact of human error-reducing technologies in the blood and tissue and cell sectors had been submitted. It was agreed that a separate teleconference would be held with Terumo to discuss these topics.

10. Medtech discussed the exemption from the tissues and cells Directive of autologous tissues and cells removed and re-applied during the 'same surgical procedure'. This is seen as leaving a regulatory gap that should be closed. In this context Medtech considers that devices, such as those used in hospitals to make platelet rich plasma (PRP), would benefit from an appropriate regulatory framework.

11. Medtech Europe thanked DG SANTE for the meeting and DG SANTE thanked them for their very useful inputs.