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 PPTA and DG SANTE B4

12 November 2019, Brussels

Summary Minutes

Participants:
Plasma Protein Therapeutics Association
DG SANTE Unit B4 Medical products: quality, safety, innovation

Upon the request, DG SANTE unit B4 met Plasma Protein Therapeutics Association (PPTA) at the premises of DG SANTE.

The purpose of the meeting was to discuss a list of topics submitted by PPTA to DG SANTE prior to the meeting, i.e. the inclusion of plasma-derived medicinal products (PDMPs) in the US-EU pharmaceutical GMP Mutual Recognition Agreement (MRA), as well as the possible inclusion of source plasma. PPTA also briefly discussed the EU Blood, Tissues and Cells (BTC) Evaluation[1] conducted by the European Commission and expressed views on the Council of Europe (EDQM) ongoing work to update the Blood Guide.

The Plasma Protein Therapeutics Association (PPTA) represents the private sector manufacturers of PDMP, and the collectors of source plasma used for manufacturing PDMPs through fractionation. PDMPs are used by patients worldwide to treat a variety of rare life-threatening, chronic and genetic coagulation diseases, as well primary immune deficiency, neurological and autoimmune disorders and albumin.

Concerning the MRA, PPTA noted that source plasma is the essential starting material for the manufacture of PDMPs and should be considered within the MRA as a biologically active substance (BAS), similarly to an active pharmaceutical ingredient (API). According to PPTA, including source plasma in the MRA would result in significant reduction of administrative and regulatory burden for plasma collection centres and authorities. According to PPTA more than 500 US plasma collection centres are currently inspected by both U.S and EU inspectors in order to fulfil specific criteria set out in the EU Plasma Master File (PMF) system so PDMPs manufactured from US source plasma collected in those centres can be marketed in the EU. The duplicate inspections of plasma collection centres result in significant burden for all parties involved, including for regulators, without any obvious benefit to medicinal

[1] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

product safety. The majority of the burden in this case is on EU inspectors as most of plasma collection centres are located in the U.S.

PPTA also mentioned that, for PDMP manufacturing facilities as well as plasma centres, current EU requirements mandate a cumbersome re-inspection of facilities every second year, and that the inspection capacity amongst EU GMP inspectors, which is already limited might decrease after BREXIT (UK being one of 3 main EU countries that inspect US plasma collection facilities).

DG SANTE explained that the next priorities for the future of the MRA are veterinary products in the first instance, and then vaccines as well as PDMPs until 2022. To this end, there is an interest in the coming years to have joint US-EU inspections on vaccines and PDMPs before considering including those products in the scope. PPTA will follow-up with the U.S FDA on the topic of joint inspections.

DG SANTE reminded that, even if source plasma is in some ways similar to other pharmaceutical ingredients, it will always be collected from human origin. PPTA and DG SANTE agreed that source plasma therefore requires it to be subject to safety and quality requirements for donation. PPTA highlighted however that specificities for source plasma collection should be recognised in these requirements, which set it apart from labile blood components – one of which that it is solely used for manufacturing and never for transfusion.

DG SANTE mentioned that the aspects of inspection frequency, and plasma specific donor requirements could be explored in a possible follow-up on the evaluation of the BTC legislation, regardless of the developments of the MRA. DG SANTE invited PPTA to collect data on the impact of double inspections and on donor requirements. PPTA stressed that donor health and safe and efficacious plasma products remain a priority for the industry and pointed to the PPTA standards programmes.

Concerning the BTC Evaluation, PPTA welcomed DG SANTE transparent approach. The association congratulated with the successful BTC conference of 28 October 2019 organised by DG SANTE which gathered around 240 stakeholders to elaborate on the results of the BTC evaluation. DG SANTE thanked for the positive feedback from the PPTA, and for PPTA's inputs to the Commission work conducted during the BTC evaluation.

PPTA acknowledged that ECDC and EDQM might play an important role in ensuring that the potentially revised BTC legislation is sufficiently adaptable to scientific, technical and epidemiological developments. PPTA emphasised the necessity for the European organisations and agencies to rely on scientific evidence and to ensure a transparent process enabling the broad range of stakeholders to provide the necessary input into their work.

On the EDQM Blood Guide, the PPTA suggested that it is important that any content represents a genuine stakeholder consensus. PPTA suggested that the association has no reservations as to a close collaboration between the Commission and the EDQM. However, PPTA does have reservations as to a possible unrestricted EU legal referencing to the Guide in the BTC legislation, given that some of the content of the Blood Guide (such as chapter 2 on plasma) is not yet mature according to the PPTA and needs further stakeholder input along the principles of scientific evidence, expert input and the observance of full procedural transparency.

DG SANTE agreed on the principles of using scientific evidence and procedural transparency and expressed openness for future PPTA inputs and collaboration.