EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

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

Meeting with PPTA (Plasma Protein Therapeutics Association)

Date: 08/06/2016

Location: DG SANTE offices

Participants

PPTA: K. Petrovsky (Senior Manager Health Policy Europe), I. Odnoletkova (Director, Health Economics and Outcomes)

SANTE: D. Schnichels, I. Siska, J. Tarkoma

Purpose of the meeting

The meeting was convened at the request of PPTA and allowed the association to express its general views and interest to contribute to the ongoing EU cooperation on HTA. The meeting allowed the Commission to explore PPTA's interest to contribute to the discussions on the future of HTA cooperation at EU level.

Discussion

PPTA's briefly introduced its mission: to promote the availability of and access to safe and effective plasma protein therapeutics for all patients in the world. PPTA represents the private sector manufacturers of plasma protein therapies and the collectors of source plasma, with new members to join.

The importance of ensuring appropriate volumes of plasma for manufacturing of plasma-derived products and the need for high levels of quality and safety were underlined. It was emphasised that new indications for plasma-derived products have been emerging, which potentially could result in fulfilling some unmet medical needs. Health technology assessment could play an important role in the future use of such products for new indications at national/EU level. PPTA emphasized that EU patients do not have equal access

to medicines/healthcare, and that the diverse organisation of the HTA systems, especially the variety of processes and methodologies, seems to be an inhibiting factor. PPTA expressed its openness to consult its member companies on their interest to participate in joint HTA, i.e. HTA performed jointly by several EU Member States (e.g. EUnetHTA joint assessments). PPTA questioned if and how this joint work is applied at national level, to ultimately benefit all patients. PPTA also emphasized the importance that the EUnetHTA secretariat provides written procedures for companies, describing processes of application and interaction between the companies and HTA bodies during the joint HTA work within EUnetHTA's Joint Action 3 Programme. Such information would be welcome to create clarity among the PPTA Members.

It was also underscored that such activities require a high level of transparency and the early involvement/interaction of all interested stakeholders.

PPTA expressed its interest to participate in stakeholders consultations organised by the EUnetHTA Joint Action 3. Other ways of participating and contributing to activities organised at EU level have been also explored.

The Commission explained that even though EUnetHTA 3 will not have a stakeholders' forum, there will be meetings with broad participation advertised in due time. It was clarified that all the necessary information will be made available on the EUnetHTA 3 website in the coming months. It was also suggested that PPTA contacts its members (industry) and enquires on their potential interest to participate to joint HTA assessments or other activities and informs directly the coordinator of EUnetHTA's Joint Action. The Commission stated that these assessments will be limited to assessing the clinical benefit. The EU heterogeneous economic landscape was seen as a significant obstacle against joint cost-effectiveness assessments. Representatives of the Commission stated that one advantage of the joint HTA work would consist in the high level of expertise ensured for assessments performed by several HTA bodies. The Commission furthermore emphasized that the coordinator of EUnetHTA 3 can also answer more specific questions from PPTA (e.g. selection and prioritisation of technologies for joint assessments).

It was also clarified that the Commission will launch a call for expression of interest of stakeholders to participate in regular meetings of the HTA Network (potential launch July-

August). Based on the applications received, a pool of stakeholders will be created, and only 2 representatives from each representative category (i.e. patients, healthcare providers, payers and industry) will physically attend the meetings. PPTA representatives underlined the need for clear selection criteria and suggested that the appointed representatives should have the obligation to circulate the information made available before meetings, collect and present the input from the other representatives in each category, and ensure the appropriate feedback after the meetings.

In addition, a public consultation should be launched by the Commission on the future of EU cooperation on HTA, which will be used for a potential initiative from the Commission on strengthening EU cooperation in this area Network (potential launch July-August). The Commission will advertise widely the consultation and the input from interested stakeholders, such as PPTA is strongly encouraged.

Conclusions

PPTA will follow the HTA policy developments at EU level and expressed its willingness to contribute to stakeholders' consultations and EUnetHTA activities. The Commission also welcomes contributions from PPTA such as publications and/or reports on cost-effectiveness of plasma-derived products. A possible other meeting between PPTA on HTA and the Commission services could be envisaged in the future.