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

# **SANTE** meeting with ECPC

Date: 24/04/2017

**Location:** DG SANTE premises

# **Participants**

**ECPC:** Prof. Francesco De Lorenzo (President), Dan Cimpoeru (Board Member), Francesco Florindi (Head of EU Affairs)

SANTE: F. Giorgio, K. Hanslik, K. Valkova

# Purpose of the meeting

The aim of the meeting is to discuss the following topics:

- 1. ECPC views on HTA
- 2. Patients' representation in HTA Network

The meeting started with a short introduction by all participants.

## Discussion

#### 1. ECPC views on HTA

The European Cancer Patients Coalition (ECPC), the largest cancer organisation in EU, laid out their views on the state of play of cancer care, from diagnosis to follow up care in Europe. The main issues were pinpointed. Firstly, it is the wide range of disparities in the access to oncological care among Member States (MS) and the variety of the national cancer plans.

According to ECPC stronger EU cooperation in Health Technology Assessments (HTA) could help in reducing inequalities in access to innovative technologies, in particular in cancer treatments. Asked by the Commission whether they could provide any data and/or figures to support this claim, the ECPC confirmed of a 17 collective law suits in Romania won by 165 cancer patients who had to wait a long period of time to get access to a new medicine (e.g. more than 6 year for Trastuzumab).

Secondly, the ECPC emphasized on the importance of sustainability when discussing the different scenarios for future EU cooperation on HTA. ECPC opposes the support for expensive treatments, which target a niche group of patients only to prolong their lives for a rather short period of time in severe conditions; and supports smart and sustainable expenditures. In this regard, ECPC considers HTA as a powerful and transparent tool to support decision makers not only for investment but also for disinvestment decisions which could free resources to be invested in innovation.

In this respect ECPC highlighted that policy option 5b of the Inception Impact Assessment is the one which would represent patients' interest in the most optimal way. ECPC understands that option 5b might luck the necessary political support to be implemented. However, ECPC stresses that any meaningful plan for future EU cooperation on HTA must at least be based on the scenario 4b, including mandatory participation and uptake of REA reports for MSs.

ECPC stressed that from what they have seen as an external partner of the Joint Action EUnetHTA, and based on their experiences and knowledge of other EU funding initiative/projects the voluntary cooperation may raise organisational issues regarding the joint production. It is important that the new initiative ensures a solid involvement of MSs to produce jointly the reports, in continuus, high quality and efficient manner.

#### 2. HTA Legal Issue

ECPC shared with the DG SANTE the analysis of the possible legal basis for the future initiative on HTA. The document analyses the Article 15 of the Directive 2011/24/EU (suggested for options 1 and 2) and the Articles 168 and 114 of TFEU and the interpretation of these articles by the Court of Justice of the European Union. ECPC considers there are certain legal barriers to the implementation of option 5b (Joint full HTA) and for this reason option 4b (Joint Relative Effectiveness Assessment) is certainly more feasible.

Furthermore, ECPC believes that the <u>Directive 2011/24/EU</u> can play a role in facilitating the implementation of the future initiative on HTA. ECPC informs DG SANTE that will provide a more detailed suggestion in writing, possibly in collaboration with ESMO.

### 3. Patients' representation in HTA Network

ECPC underlined the importance of including patients' organisations in HTA processes. ECPC is involved in the Joint Action on Cancer Control. While the ECPC is not formally part of EUnetHTA for now, they underlined the importance of incorporating best practices of patients' involvement in future HTA cooperation. ECPC referred to EMA cooperation as a good example of involving patients.

#### Follow up

The ECPC thanked DG SANTE for the meeting and expressed their willingness to continue the dialogue with the Commission. They will remain at the Commission's disposal to provide any hard facts on the positive role strengthening cooperation on HTA, including harmonisation in certain areas could bring to improving the function of the Internal market and the overall objective of better access to medicine for patients.

DG SANTE was invited to the ECPC event on 25 April 2017 in the European Parliament to present the preliminary results of the public consultation on HTA.