ECC2015 Special Session
"European Regulation And Health Technology Assessments In Immunotherapy"
Monday 28 september 2015
Room: Stolz 2
11:30-12:30

In the EU, the centralized procedure (CP) of the European Medicine Agency (EMA) is mandatory for marketing authorization for innovative anticancer drugs. A CP will result in one marketing authorization for all Member States granted by the European Commission. At variance, numerous independent healthcare systems are in operation across the EU, and each Health Technology Assessment (HTA) body follows its own methodologies and scientific value judgements in the assessment of the added value of an innovative anticancer drug. Payers in the various member states consider these assessments to a varying degree as input in their pricing and reimbursement negotiations. At the same time international reference pricing and parallel trade have an inherent tendency to establish rather uniform price levels across member states. Consequently, drug access for patients differs considerably within the EU.

The session will focus on the European regulation and Health Technology Assessment (HTA) appraisals of novel immuno–oncology products, address hurdles and explore potential solutions.

PROGRAMME

Moderator: John Smyth (CDDF Board member - The University of Edinburgh, UK)

11:30 Introduction
John Smyth (The University of Edinburgh, UK)

11:35 Immunotherapy - a new challenge for Regulators?
Francesco Pignatti (European Medicines Agency, UK)

11:50 Comparing apples with oranges - how to assign real value?
Bruno Flamion (University of Namur, Committee for Reimbursement of Medicines, Belgium)

12:05 How effective is the public in influencing HTA decisions?
Francesco De Lorenzo (European Cancer Patient Coalition / former member of the italian parliament and former minister of health, Italy)

12:20 Discussion

12:30 End of the session