Curriculum – EU Network Training Centre: Oncology pilot educational program for external experts

Part 1: General Regulatory curriculum

#	Topic	Contents	Presenter
G1	Introduction: Overview of the regulation of medicines in Europe	The overall objective: protecting patients Regulators' role in the life cycle of a medicine The European medicines regulatory network EMA's committees Mandate of CHMP and how CHMP works	Harald Enzmann CHMP chair Head of European & International Affairs, BfArM - Germany
G2	How does scientific advice work?	The mandate of Scientific Advice Working Party (SAWP) and how it works Brief description of the various tasks Interaction with other bodies/ committees/ working parties Examples of what is in/out of scope of the SAWP	Paolo Foggi SAWP chair Head of Innovation and Pharmaceutical Strategy Division, AIFA - Italy
G3	How do centralised procedures work?	Procedural steps of initial applications, type 2 variations and extensions Time tables leading to decision making in centralised procedures at the CHMP	Martin Norta Head of procedure management, BfArM - Germany
G4	Propaedeutic for benefit-risk assessment	The basics of benefit risk assessment as the basics of regulatory decision making, with the focus on clinical efficacy and safety	Francesco Pignatti Scientific adviser for Oncology, EMA -The Netherlands
G5	Input CTD application, Output regulators' assessment report	Explaining the eCTD structure and how the European Public Assessment Report evolves from it	Francesca Day Head of Therapeutic Areas Department, EMA -The Netherlands
G6	Case studies	Selection of examples, positive and negatives based on EPAR	Several speakers

Part 2: Oncology-specific curriculum

#	Topic	Contents	Presenter
S1	Overview of EMA-approved anti-cancer products	High level overview on all centrally authorised oncology substances, based on mechanism and specific molecular target	Harald Enzmann CHMP chair Head of European & International Affairs, BfArM - Germany
S2	Overview of relevant guidelines	Orientation on relevant oncology guidelines and reflection papers; How to use guidelines in assessment	Francesco Pignatti Scientific adviser for Oncology, EMA -The Netherlands
S3	Efficacy endpoints in oncology	Acceptability of endpoints for solid tumors and haematological malignancies, incl. particularities of MAUEC, CMA	Francesco Pignatti Scientific adviser for Oncology, EMA -The Netherlands
S4	Biomarkers and companion diagnostics in oncology	Biomarkers in initial assessment of a new medicine. Current status: previously approved products with biomarker. Cooperation with notified bodies in consulting procedure	Harald Enzmann CHMP chair Head of European & International Affairs, BfArM - Germany