European Federation of Allergy and Airways Diseases Patients' Associations

EFA Meet and Greet the EU training

The European Medicines Agency

14th of June of 2021, 13h-17h15, online webinar

Context: The EFA Meet & Greet the EU training is part of the EFA capacity building programme for 2020

Objective: INFORM - Provide meaningful input, skills and competences to EFA Members and expert patients from other respiratory diseases interested in participating in regulatory processes for medicines development.

Target audience: Staff, volunteers and members of the Board of EFA members. Open also to patients non-attached to an EFA member, provided they belong to patient groups active in the field of respiratory disease.

Time	Topic	Presenter	Online Materials
13h00-13h15	**Welcome** • Importance of allergy and respiratory patient involvement in decisions that affect them • Objectives of the meeting	Isabel Proaño, Director of Policy and Communications (EFA)	
13h15-14h15	**Authorisation of medicines in Europe and patient involvement** Regulatory pathway of medicines in Europe: • Introduction to EMA and the review of its mandate • Methodologies for patient organisations and patient engagement and support • Patient involvement in EMA and its impact Case study of EFA patients involved in the past Discussion	Maria Mavris, Patient Relations, Public and Stakeholder Engagement department (EMA)	The European Medicines Agency (video) The EMA centralised procedure (video) How the EMA interacts with patients and consumers (video) EMA-PCWP patients and consumers working party (video)
14h15-14h25	**Comfort break**		
14h25-15h30	**Information and patient involvement in practice** Assessment of patient participation in the processes for respiratory medicines: • Patient review of medicinal product information and safety information • Scientific Advice Procedures • Participation in Scientific Advisory Groups (SAGs) Practical exercise: reviewing a document Feedback, Questions and Answers	Maria Mavris (EMA)	How are patients involved in the review of documents? (video) What is scientific advice? (video)
15h30-15h40	**Comfort break**		

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15h40-16h00	**Red tape** How to fill in the administrative forms at EMA and support available: • Conflict of interest • e-CV Questions and answers	Susanna Palkonen, Director (EFA) Erna Botjes, EFA representative at EMA (EFA)	Declarations of interest: a practical guide (video)
16h00-16h45	**Safety: pharmacovigilance and safety monitoring of medicines for allergy and respiratory disease** • Product lifecycle • Monitoring adverse reactions Feedback, questions and answers	Sabine Straus, Chair of the EMA Pharmacovigilance Risk Assessment Committee (PRAC)	Pharmacovigilance (video) What is a European safety referral (video)
17h00-17h15	**EFA network pool of expert patients** Wrap up and closing	Isabel Proaño (EFA)	

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