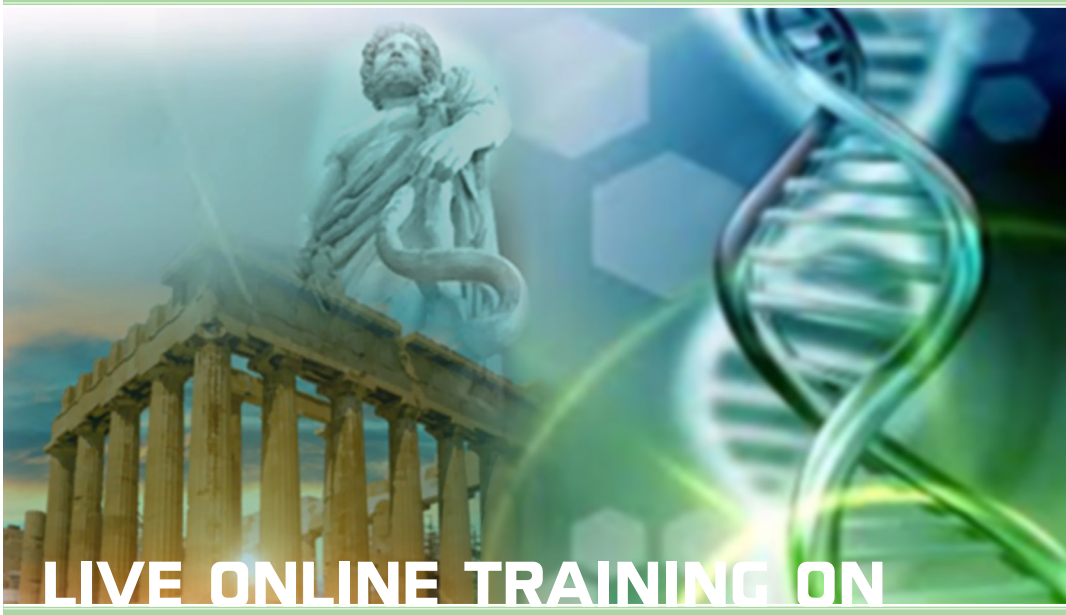
Seminar of the Panhellenic Association of Pharmacists (PEF)

From Regulatory To PHARMACOVIGILANCE

Pharmacovigilance Referrals And Regulatory Framework With Focus In Oncology



LIVE ONLINE TRAINING ON

18 NOVEMBER 2020

17:00 - 21:00 pm

HIGHLIGHTS

- Marketing Authorization Assessment in the EU
- Evaluation of oncology products at EMA
- Pharmacovigilance referrals
- Initial marketing authorization application for centralized procedure products
- Mutual, decentralized and national eCTD format submission dossier
- Oncology medicinal products marketing authorization

SPEAKERS

EUROPEAN MEDICINES AGENCY

1. Efstratia Vatzaki, EMA
2. Nikolaos Zafiropoulos,EMA
3. Aikaterini Nikolaou, EMA

AIFA

4. Amelia Cupelli, AIFA

Εθνικός Οργανισμός Φαρμάκων
National Organization for Medicines

5. Dr Demetrios Filippou, EOF
6. Konstantinos Ghirtis, EOF

PHARMASSIST
CONTRACT RESEARCH ORGANISATION

7. Sophia Bogri, Pharmassist LTD, CRO

TARGET AUDIENCE

This course addresses to staff from Regulatory Affairs, Pharmacovigilance, and Quality Management. This involves Regulators, Pharmaceutical Industry Leaders, Senior and junior staff as well as University Students in relevant disciplines (e.g. Pharmacy, Chemistry, Medicine, etc.).

AGENDA & MEETING SCHEDULE

17:00 - 17:05 — **Welcome**

Sofia Trantza, President of the Panhellenic Association of Pharmacists (PEF), PharmD, MSc, MSc PV

17:10 - 17:15 — **Opening of the seminar**

Vasilios Kontozamanis, Undersecretary of Greek Ministry of Health

17:15 - 17:25 — **National Organization for Medicines (EOF) and its connection with the European Medicines Agency (EMA)**

Dr Demetrios Filippou, President of the National Organisation for Medicines (EOF)

17:30 - 18:30 — **Session 1: Pharmacovigilance referrals**

Coordinator: Andri Andreou, PharmD, M.MedSc, MBA

17:30 - 18:00 — **PhV referrals:**

An overview Aikaterini Nikolaou, EMA

An overview of PhV referral procedures will be presented including Article 31 and 107i of Directive 2001/83/EC and Article 20 of Regulation (EC) 726/2004.
The presentation covers various aspects of these procedures such as:

- Who can trigger a referral,
- What is the scope of the procedure,
- What is the assessment process and the timelines,
- What are the possible outcomes and how the outcomes are implemented

18:00 - 18:30 — **Referrals and PhV in public service: Cases and solutions**

Dr Efstratia Vatzaki, EMA

How the European system uses the knowledge and resources available in critical times to provide unified solutions for all European Citizens: Zinbryta, Valproate and Dexamethasone

18:30 - 18:45 / BREAK

18:45 - 20:45 — **Session 2: Regulatory framework with focus in oncology**

Coordinator: Dr Dimitra Ioanna Lampropoulou, Clinical Pharmacist, PharmD,MSc, PhDc

18:45 - 19:15

Mutual, Decentralized and National submission Dossier in eCTD format

Sophia Bogri, Senior RA officer, Pharmassist LTD, CRO

- Marketing Authorisation of medicines (via National / Procedure, DCP and MRP)
- Renewal of Marketing Authorisation of medicinal products
- Type IA, IB and II variations
- Article 61(3) changes
- eCTD compilation and publishing CESP submissions

19:15 - 19:45

Regulatory framework of Marketing Authorization Assessment in the EU: An ongoing procedural and scientific exercise

Dr Konstantinos Ghirtis, EOF

In this talk, the EU legislative and regulatory framework, its strengths and weaknesses are reviewed from an assessor' s point of view.
Illustrative examples shal be provided to stimulate discussion."

19:45 - 20:15

Evaluation of oncology products at EMA

Nikolaos Zafiropoulos, EMA

- How we coordinate the network of experts, internally and externally,
- How we meet the expectations of prescribers and patients,
- How we evolve the benefit-risk assessment in oncology,
- International collaborations at regulatory and academic level,
- Engagement in relevant projects and scientific initiatives in the area of oncology

20:15 - 20:45

Initial marketing authorization application for centralized procedure and continuous monitoring with focus in oncology

Amelia Cupelli, PRAC member, AIFA

- Initial MA application for centralized procedure with focus in oncology
- After initial authorization, continuous monitoring (RMP, PSUR assessment) with focus in oncology

20:45

Closing

Conference language

The official conference language will be Greek and only English for non- native speakers.

Technical Requirements

You may watch the seminar online through the website www.livemed.gr/en/live

Upon confirmation of your registration (and 2 days prior to the event), you will receive at your e-mail the username and password that will allow you to access the online platform.

Fee for the seminar

PEF members: 200 EUR

PEF non-members: 250 EUR

Students and unemployed: 50 EUR

In all above fees, VAT is included.

PEF members should have updated their subscription fee even for 2020.

Students and unemployed should demonstrate their studentship and unemployment though official proof.

Certificates of attendance will be provided.

Registrations

All registrations to the seminar will be performed following the opposite link in the official site of PEF from the official date of announcement.

https://forms.gle/MpqqyAwYUHYgTgKY8

Fees payable at

IBAN: GR91 017 143 500 064 350 100 707 31,

Piraeus Bank

In case of interbank transaction, please bear the costs of the transfer to the account of PEF.

Organization and Contact

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