"Regulatory aspects of drug development in Europe"

12th of October from 4:00pm – 7:00 pm CET

Online workshop of the COST Action CA21111
One Health drugs against parasitic Vector-borne diseases in Europe and beyond (OneHealth*drugs*)

The event is open to COST and non-COST participants from both academia and pharma

Description. The *One Health approach* recognizes the interconnectedness of human, animal, and environmental health, aiming to address planetary health issues, including parasitic diseases, through a holistic and collaborative approach. When it comes to drug development for Parasitic Vector-Borne Diseases (PVBDs), there are several regulatory aspects that should be analyzed under the *One Health* framework for an effective multidisciplinary collaboration, towards sustainability of drug development, its production and distribution. Therefore, to meet the *One Health* approach expectations for drug development against PVBDs, careful consideration of regulatory aspects that encompass human and animal health, ethical concerns, environmental impact, and international collaboration must be considered. Effective communication and coordination among regulatory agencies, researchers, and stakeholders are essential to bring safe and effective drugs to both humans and animals.

At "Regulatory aspects of drug development" we aim to enlightening COST Action 21111 participants and partners on some fundamental aspects for Drug Development Regulations in Europe, and how they imply in the drug development and distribution of drugs for human and animal PVBD.

Programme (CET)

16:00 to 16:05 - Opening and introduction by WG.6 Leader, Clara Lima
16:05 to 16:15 - Introduction by the COST Action 21111 Chair, Maria Paola Costi, University of Modena, Italy.
16:15 to 16:45 - "Considerations on European Regulations for marketing authorizations of new drugs" + Dr. Dina Lopes. INFARMED, Portugal
16:45 to 17:15 – " Veterinary VBDs and Regulatory Challenges in Europe" + Dr. Yann Toussain. Boehringer Ingelheim, Germany.
17:15 to 17:45 - "Drug development – From bench to bedside" + Dr. Ricardo Cunha, Bluepharma, Portugal.
17:45 – 18:00 - Q&A
18:00 – 19:00 - Round table discussion on **"OneHealth requirements for responsible human and animal drugs prescription. Recommendations from EMA"** .

For non-COST participants, registration requires two steps :
1) create an **e-COST** account at www.cost.eu
2) register here: **https://docs.google.com/forms/d/e/1FAIpQLScDI1TzZO6kRmn5916-dtVQUzusuxcGkc_dclCxIMpdfpiaBA/viewform?usp=sharing by the 10/10/2023**