

Safeguarding patient safety and quality of care in Europe: Good practice for off-label use of medicines

27 September 2016

10:00-12:00

European Parliament

Room: ASP A1E2

Objective

The objective of the event is to raise awareness among EU decision-makers and stakeholders about the off-label use of medicines and the importance of set clear guidelines in this regard to ensure the safety of European patients. The event is also an opportunity to present the Declaration on Good Off-Label Use Practice and build consensus among stakeholders about best practices in this area.

Agenda and Speakers

Moderator: **Frédéric Destrebecq, Executive Director, European Brain Council**

10.00-10.10 **MEP Piernicola Pedicini (EFDD ENVI Coordinator)**

Welcome speech

10.10-10.20 **Marc Doms, hospital pharmacist and author of the Good Off-Label Use Practice**

Setting up criteria for the safe use of medicines off-label

10.20-10.30 **Guy Goodwin, Professor of Psychiatry at the University of Oxford and President of the European College of Neuropsychopharmacology**

An overview of the off-label use in psychiatry

10.30-10.40 **Francois Houyez, Director of Treatment Information and Access, EURORDIS**

Views of patients with rare diseases and good practices on off-label use

10.40-10.50 **Mike Isles, Executive Director, European Alliance for Access to Safe Medicines**

The risks of the unregulated use of medicines off-label for patient safety

10.50-11.00 **James Killick, Partner, White & Case LLP**

The off-label use in the context of the EU regulatory framework for medicinal products

11.00-11.10 **Andrzej Rys, Director for Medical Products and Innovation, DG Santé, European Commission**

The European Commission's role and position on the off-label use of medicines

11.10-11.40 **Questions & Answers**

11.50-12.00 **MEP Piernicola Pedicini (EFDD)**

Closing remarks

12.00-13.00 **Reception**