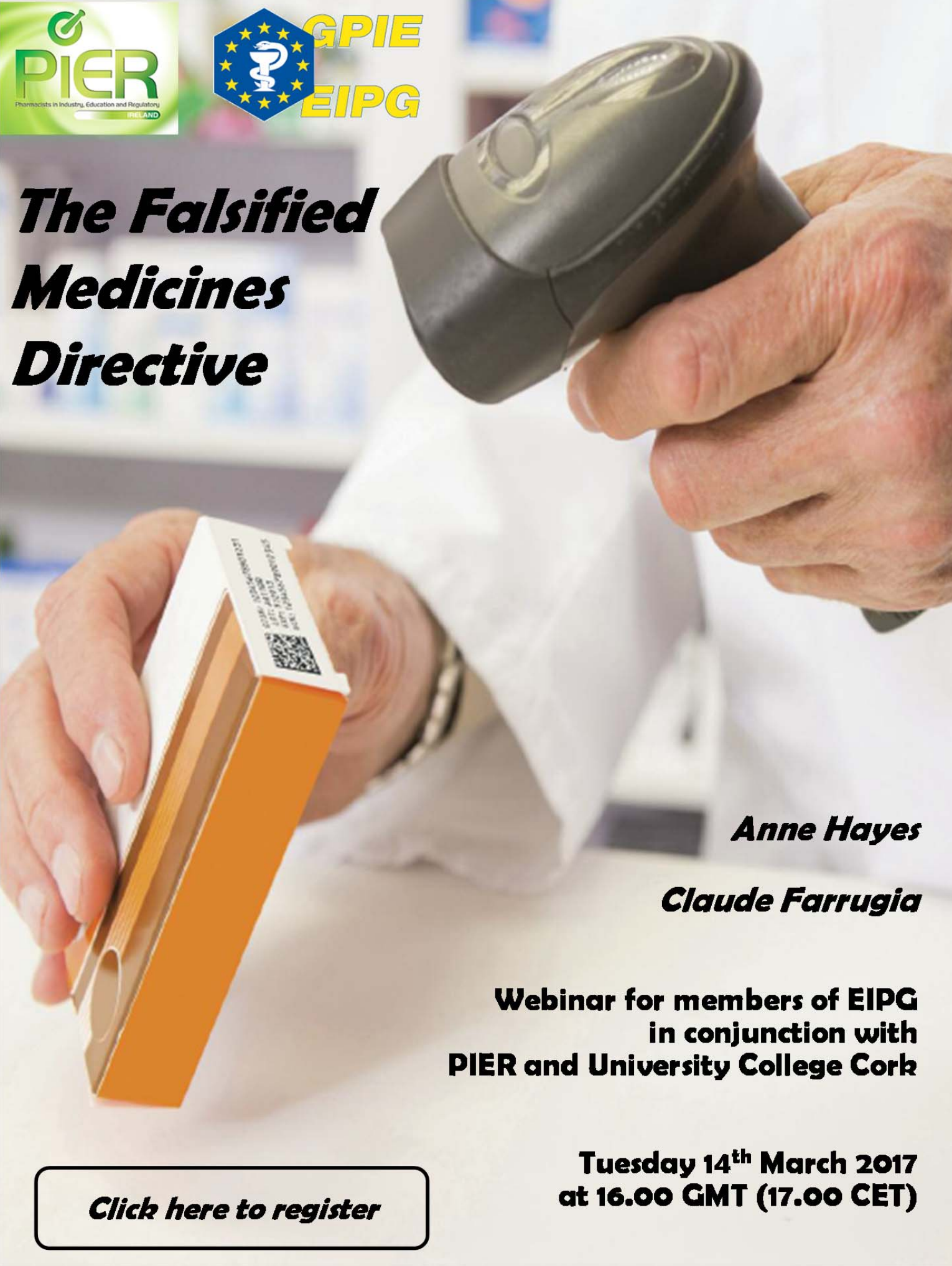




The Falsified Medicines Directive



Anne Hayes

Claude Farrugia

**Webinar for members of EIPG
in conjunction with
PIER and University College Cork**

**Tuesday 14th March 2017
at 16.00 GMT (17.00 CET)**

Click here to register

Overview of Webinar

In 2011, the European Commission (EC) published Directive 2011/62/EU, the Falsified Medicines Directive (FMD), which amended Directive 2001/83/EC to address concerns about the increasing threat of ‘falsified’ medicines. One aspect of the FMD deals with the introduction of a system that will enable manufacturers, wholesale distributors and everyone who supplies medicines to patients to verify the authenticity of individual packs and check whether they have been tampered with. The details of this system were described in Delegated Regulation 2016/161, which shall apply from February 2019. The opening speaker, Anne Haynes, will discuss the changes in the manufacturing and supply chain requiring a new legislative framework, while Claude Farrugia will consider the current status of the unique identifier and quality systems.

About the Speakers

Anne Hayes currently holds the position of Inspection Manager within the Compliance Dept at HPRA. Her qualifications and expertise span across legislation and policy relating to inspections in the field of GMP, GCP, blood, tissues and cells, organs for transplantation, pharmacovigilance and medical devices to Health and Pharmaceutical Manufacturing Technology. She is a Joint Audit Programme auditor/ trainer and GMP expert Member of the EMA Incident Review Network. She is also a member of PIC/S. As Inspection Manager, she has an in-depth knowledge of the Falsified Medicines Directive.

Claude Farrugia is the current President of the European Industrial Pharmacists Group (EIPG), having previously served as the organisation’s Vice-President Communications from 2008 to 2016. He has experience as a contract Qualified Person, and Quality Assurance and Regulatory Affairs consultant. He is closely linked with the pharmaceutical industry in Malta, as Chairman of the Pharmaceutical Manufacturers Business Section within the Malta Chamber of Commerce, Enterprise and Industry. He is an Associate Professor in Applied and Biological Chemistry at the University of Malta, with research interests in the field of applied chemistry in the pharmaceutical industry.

To Join the Webinar

Please register for the event by filling out the form at https://docs.google.com/forms/d/e/1FAIpQLSfTRLR6uIcq0ergRr2s5XryD7cCkPDw_5UEX3F6Maa6lkuIHA/viewform . Instructions will be sent by e-mail.

Continuing Education

A certificate of attendance will be issued after the webinar if requested upon registration, and if the evaluation form is completed. The session will be an hour of Continuing Education.