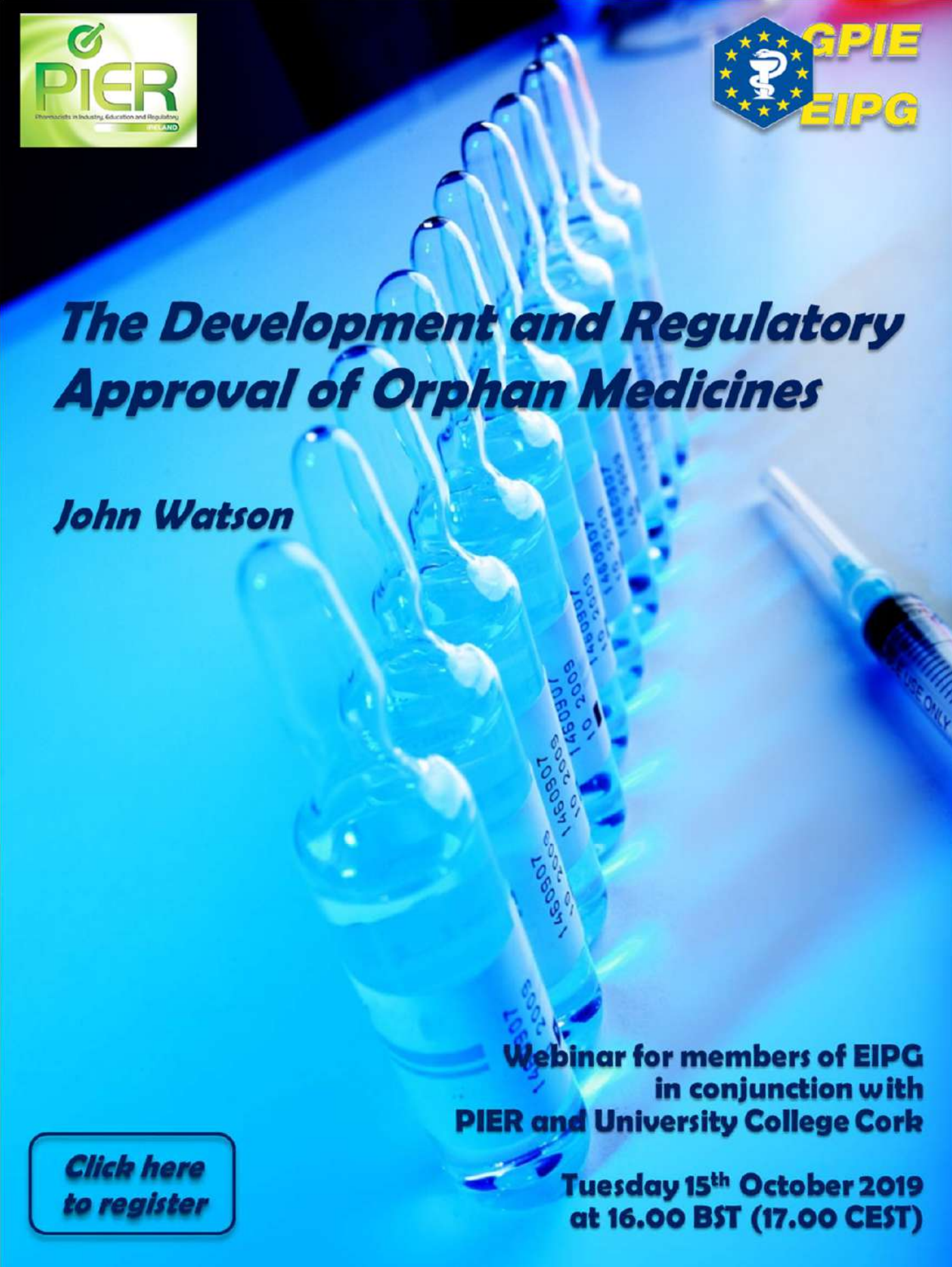
PIER
Pharmacists in Industry, Education and Regulatory
IRELAND
GPIE
EIPG
The Development and Regulatory Approval of Orphan Medicines
John Watson
Webinar for members of EIPG
in conjunction with
PIER and University College Cork
Tuesday 15th October 2019
at 16.00 BST (17.00 CEST)
Click here to register

About the Speaker

John Watson BSc MBA MTOPRA has worked for four SME biotechnology companies and several large pharma companies. He currently works for Zogenix International Ltd as Head of Regulatory Affairs Europe. John has vast experience in the strategy, preparation, submission, negotiation of approval and maintenance of medicines regulated using the EU centralised procedure including twenty Marketing Authorisations. He has planned and managed the development and submission of eight orphan medicine applications, and many CHMP and national scientific advice procedures.

Overview of Webinar

40 years ago, rare diseases and the development of medicines to treat them were not being addressed. Investment, research and development focussed on diseases where populations were large and the likely return on investment was favourable. Today, orphan medicines are rising stars. Some of the world's best-selling medicines are for the treatment of orphan diseases. The potential return on investment is favourable and large pharma companies have grown their own and acquired rare disease companies. There are also hundreds of start-ups, blooming across the USA and Europe attracting funding and investment. This webinar will describe how legislative changes incentivised research and development in rare diseases, the pathways and procedures to develop and approve new orphan medicines and where to find trusted information. The webinar will cover the development and regulatory approval of orphan medicines in the European Union.

Leaning Outcomes

By the end of this presentation, you will be able to:

1. Define what is meant by an orphan disease
2. Define what is meant by an orphan medicine
3. Understand the incentives available to develop new orphan medicines
4. Appreciate the special needs for the development of orphan medicines for children
5. Consider the importance of re-purposing older medicines for the treatment of orphan diseases
6. Consider formulation and supply problems specific to some orphan medicines
7. Understand the lifecycle of an orphan medicine, including applying for orphan designation, applying for a Marketing Authorisation application for an orphan medicine, and post-authorisation activities
8. Find trusted information on orphan diseases and medicines

To Join the Webinar

Please register for the event by filling out the form at https://docs.google.com/forms/d/e/1FAIpQLSd1H5gzNKMpNBHb9b3_qmb6mfx-b3RWCXRCKtrseXXdN_YTIg/viewform. Further instructions will then be sent by e-mail.

Continuing Education:

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.