FACULTY OF HEALTH AND MEDICAL SCIENCES

UNIVERSITY OF COPENHAGEN

Copenhagen Centre for Regulatory Science (CORS)
Medical Product Innovation - Research & Education

Annual Conference of the Copenhagen Centre for Regulatory Science (CORS)

” Transparency in drug regulatory decision making – opinions, examples and perspectives”

Holst Auditorium, Mærsk building

2nd of October 2017

This conference will focus on ‘transparency in drug regulatory decision making’. As a part of the increasing focus on promoting regulatory transparency, several initiatives have centred on utilising structured approaches to support regulatory decision-making processes and the communication of the outcomes of those assessments. Invited speakers will represent the relevant stakeholders such as regulators, industry, academia and patients. The representatives will present their views on the efforts to improve transparency in regulatory decision-making and future needs to accommodate transparency in regulatory decision-making balancing the Protection of Personal Data (PPD) as well as Commercial Confidential Information (CCI)

Conference organizing committee:
Professor Timo Minssen Centre for Information and Innovation Law, Merete Schmiegelow Novo Nordisk, Birthe Holm Rare Diseases Denmark , Mathias Møllebæk Copenhagen Center for Regulatory Science, and Christine Hallgreen Copenhagen Center for Regulatory Science

Preliminary Program

9:00	*Welcome: Professor Marieke De Bruin, Copenhagen Center for Regulatory Science, University of Copenhagen, University of Copenhagen*
9:15	*Session 1 – Why transparency? – benefits and risks* *Chair:* Merete Schmiegelow, Honorary Industrial Ambassador, Faculty of Health and Medical Sciences, University of Copenhagen Regulatory perspective, *to be announced* Patient perspective, Birthe Holm, Rare Diseases Denmark Industry Perspective, *to be announced*
10:30	*Break*
11:00	*Ragnar Löfstedt, King College London* *Topic: ''Concept of transparency in policy and regulatory decision-making'*
12:00	*Lunch*
13.00	*Session 2: The information is there but is that transparency?* *Chair: Sinan B. Sarac, Danish Medicines Agency* Dominic Way, King College London Topic: 'Transparency in drug regulation in EU and the US' Mathias Møllebæk, Copenhagen Centre of Regulatory Science (CORS) Topic: 'Transparency and communication - the case of safety warnings', Larry Liberti, Centre for Innovation in Regulatory Science (CIRS) Topic: 'Benefit-risk and transparency' Asbjørn Nøhr-Nielsen, Copenhagen Centre for Regulatory Science (CORS) Topic: 'Using data from EPARs in research - Public available and transparent?'
15:00	*Break*
15:30	*Session 3 – Perspectives and opportunities* *Chair: Professor Timo Minssen, Centre for Information and Innovation Law, Faculty of Law* Nicholson Price, University of Michigan Law School Topic: 'Black box medicine and regulation', Panel discussion
16:45-17.00	*Closing remarks: Professor Marieke De Bruin*