"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, Honorary Industrial Ambassador, University of Copenhagen, Birthe Holm Rare Diseases Denmark, Mathias Møllebæk Copenhagen Center for Regulatory Science, and Christine Hallgreen Copenhagen Center for Regulatory Science
Program

9:00  Welcome: Professor Marieke De Bruin, Copenhagen Center for Regulatory Science, University of Copenhagen, Denmark

9:15  Session 1 – Perspectives on transparency in regulatory decision making - Why transparency?  
Chair: Merete Schmiegelow, Honorary Industrial Ambassador, Faculty of Health and Medical Sciences, University of Copenhagen

Anne-Sophie Henry-Eude, Document Access and Publication Service, EMA
Birthe B Holm, Rare Diseases Denmark
Jesper Kihl, Vice President, Regulatory Affairs, Leo Pharma A/S (to be confirmed)

10:30  Break

11:00  Professor Ragnar Löfstedt and Dominic Way, King’s College London, UK and  
Topic: ‘Concept of transparency in policy and regulatory decision-making’

12:00  Lunch

13:00  Session 2: Experiences with communication and information of regulatory decision making  
Chair: Sinan B. Sarac, Danish Medicines Agency

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), UK  
Topic: ‘Benefit-risk and transparency’

Asbjørn Nøhr-Nielsen, Copenhagen Centre for Regulatory Science (CORS)  
Topic: ‘Using data from EPARs in research - Publicly available and transparent?’

15:00  Break

15:30  Session 3 – Future perspectives, risks & opportunities  
Chair: Professor Timo Minssen, Centre for Information and Innovation Law, Faculty of Law

Nicholson Price, University of Michigan Law School, USA  
Topic: ‘Black box medicine and regulation’

Timo Minssen, University of Copenhagen  
Emerging minefields at the interface of data transparency, IPRs, trade secrets & data protection


16:45  Closing remarks: Professor Marieke De Bruin, Copenhagen Center for Regulatory Science, University of Copenhagen, Denmark

17:00  End of the meeting