VIVE seminar:

“Breakdown? Are we seeing fundamental changes in the development, use and governance of medicines and what might this mean for all of us?"

Prof. Paul Martin from Sheffield University is visiting the VIVE – The Danish Center for Social Science Research. At this seminar, Prof. Paul Martin outlines how a marked shift in the development, use and regulation of medicine has happened during the past couple of decades possibly turning the ’rare’ into the ’new normal’. Further, he will open up for discussion about the long-term implications of the observed developments. After the talk, discussion will continue over a glass of wine.

When: 11th of Maj at 2:30-4:00 pm

Where: VIVE – The Danish Center for Social Science Research, Herluf Trollesgade 11, Copenhagen

Registration: Please sign up before the 5th of May through this link.

Abstract:
A series of major transformations and transitions are underway in the production, regulation, marketing and use of medicines. This impacts on both the pharmaceutical industry itself, as well as the organisation of healthcare and the relationship between companies, professionals and patients. These changes centre around the rapidly increasing importance of advanced therapies and so-called “orphan drugs” for rare diseases, named after the 1983 US Orphan Drug Act (ODA). Over the last two decades orphan drugs have moved centre stage within the pharmaceutical sector and now constitute more than half of new drug approvals by the US FDA each year. Advanced therapies (ATMPs) based on tissue engineering, cell and gene therapy represent the next generation of therapeutic innovation and many also target rare diseases. Accompanying the development of these new technologies have been a number of key changes, including: , 1) Novel industry business models that seek to create highly priced products for niche markets; 2) New regulatory regimes including expedited review processes, conditional approval and new forms of evidence; 3) Innovative technology assessment and reimbursement models; 4) The establishment of services and infrastructures to support the use of highly specialised orphan drugs and complex advanced therapies; 5) Changing relationships between the pharmaceutical industry and rare disease patients; and 6) New discourses of disease aetiology that place greater emphasis on the genetic origins of disease. Collectively these changes can be seen as constituting a transition in the sociotechnical regime associated with the pharmaceutical sector that has much wider implications beyond the field of rare diseases. It raises profound questions about access, equity and the long term sustainability of healthcare systems and the industry itself. This paper will establish a robust conceptual framework based on the notion of “orphanisation” to analyse these changes and their implications for the future of the pharmaceutical industry, the governance of innovation, the structure of healthcare systems and the biopolitics of contemporary medicine.