Section 3

Philosophy of Pharmacology: Theoretical Foundations, Methodological Evolution, and Public Health Policy

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Participants: Michael P Kelly (University of Cambridge), Rani Lill Anjum (Norwegian University of Life Sciences), Elena Rocca (Norwegian University of Life Sciences), Ralph Edwards (WHO/ Uppsala Monitoring Center)

Abstract:

The complex network of interests (financial, reputational etc.), as well as legal rights and duties that frame the scientific and social ecosystem in which pharmacology is embedded, make it a unique blend of science and technology. In this symposium philosophers and health scientists provide a panorama of the complex interaction of such heterogeneous dimensions with a special focus to the current debate on 1) standards for evidence evaluation, 2) methodological evolution, and the 3) pragmatics as well as epistemic asymmetry of causal assessment of risks vs. benefits. All contributions touch these points from a different viewpoint.

Titles and Abstracts of the talks

1.
Michael P Kelly: The philosophical and methodological pathways to Medicines Adaptive Pathways to Patients (MAPP).
The development of Medicines Adaptive Pathways to Patients (MAPP) has been driven in part by the desire to make new technologies available more quickly to patients especially in the case of rare diseases, but also by a recognition that the RCT as a basis for decision making in the era of genomics and personalised medicines may be nearing the end of its shelf life. This paper presents the debate on the development of MAPPs and suggests that by exploring the philosophical and methodological provenance of MAPP we can describe a narrative of EBM and Health Technology Assessment in which "normal science" can be seen to be operating rather than as some have proposed, a paradigm shift.

2.
Rani Lill Anjum and Elena Rocca: Underdetermination and Ontology of Causation in Pharmacology
Causation in pharmacology is characterized by underdetermination in several respects, both related to its contextual character, and to the intrinsic ontology of chemical reactions.
We analyse such phenomena from a dispositionalist point of view (Mumford and Anjum 2011) and motivate an explorative approach to causation. The framework explains why cases of causal failure, if properly acknowledged, provide opportunities for new insights, paving the way for deep causal knowledge. Furthermore, the context-sensitive, intrinsic, tendential and complex nature of causation explains why we should expect that new information comes to light in the post-marketing phase, especially about off-target effects. Accordingly, we argue

in support of a better integration of post-marketing monitoring with the other phases of pharmacological research.

3.
Ralph Edwards: Causality in Pharmacovigilance: small harms – big problems
Most individual drugs are a rare cause of clinically important harm, but the very many different products available, and their widespread use, results in a global public health concern.
Causal involvement by drugs in harm is multifaceted, ranging from causation by a single drug, through contingent and contributory causation in therapy, to problem of misuse and medication errors: the causal chain may be very complex and multiple methods are needed to determine causality using iterative Bayesian approaches .
Clinicians need useable information to help them prevent causing harm in risk situations; to enable early diagnosis; and to manage patients. All vectors impinging on individual causation need exploring.

4.
Barbara Osimani: Statistics in Pharmacology – from an epistemological point of view
The talk analyses statistical issues in pharmacology from the perspective of formal and social epistemology. This perspective illuminates both foundational issues related to how concerns about "second order" dimensions of evidence, such as suspected vested interests (of financial or "scientific" nature) are incorporated in the inferential protocol, as well as current debates related to the so called "reproducibility crisis" (Gelman 2015, Marsman et al. 2016), various forms of bias (Krauth et al. 2013), and best methods for evidence synthesis (Landes et al. 2016).
I illustrate such research program by presenting the results of a formal model of scientific inference (Landes, Osimani, forthcoming) where we explicitly model the interaction of reliability, consistency of replications, dependence of observations, and the distinctive role of random vs. systematic error in hypothesis confirmation. While our results differ from both Bovens and Hartmann, 2003 as well as Claveau, 2013, they are in line with recent simulation studies on the epistemic gain of replication (Romero, 2016).