CLINICAL INNOVATION: Fair & Effective Incentives for New Uses of Established Drugs

The Regulators' Perspective

Moderator: Brian Cordery *Bristows LLP*

Panellists:

- **Prof. Sir Alasdair Breckenridge CBE** *Former Chair of MHRA, UK*
- **Stefano Marino** *Head of Legal, European Medicines Agency*
- **Daniel Kracov** *Arnold & Porter Kaye Scholer LLP*

Introductory remarks

Alasdair Breckenridge

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Issues

- Market access is determined by regulation and health technology assessment
- Benefit risk of the same medicine will vary in different indications
- Dose response relation of a medicine will vary when the responses differ
- Regulatory science moves on. Previous standards (e.g. in preclinical studies) may not be acceptable in a repurposed indication

Market access

- Market access is determined by regulation and health technology assessment
- Medicines regulation is determined by considerations of safety, quality and efficacy
- Health technology assessment comprises considerations of comparative clinical efficacy and cost effectiveness

Benefit risk balance

- Marketing authorisation of a medicine is determined by its benefit risk balance.
- Benefit risk balance will vary when the same drug is used in different indications.

e.g. Herceptin in advanced and early breast cancer

Dose response relationships

- Dosage is critical to obtain an optimal therapeutic response
- In different indications, since the responses differ, so will the dose response relationship
- Assessment of dose is important in repurposing

Standards in regulatory science

- Regulatory science has progressed over time
- Previous standards may no longer be acceptable
- Previous preclinical data may no longer be acceptable in a repurposed situation

    e.g. 5-HT2 agonist in anxiety and drug resistant depression