Debates About Accelerated Access to Medicines: Reality or Rhetoric?
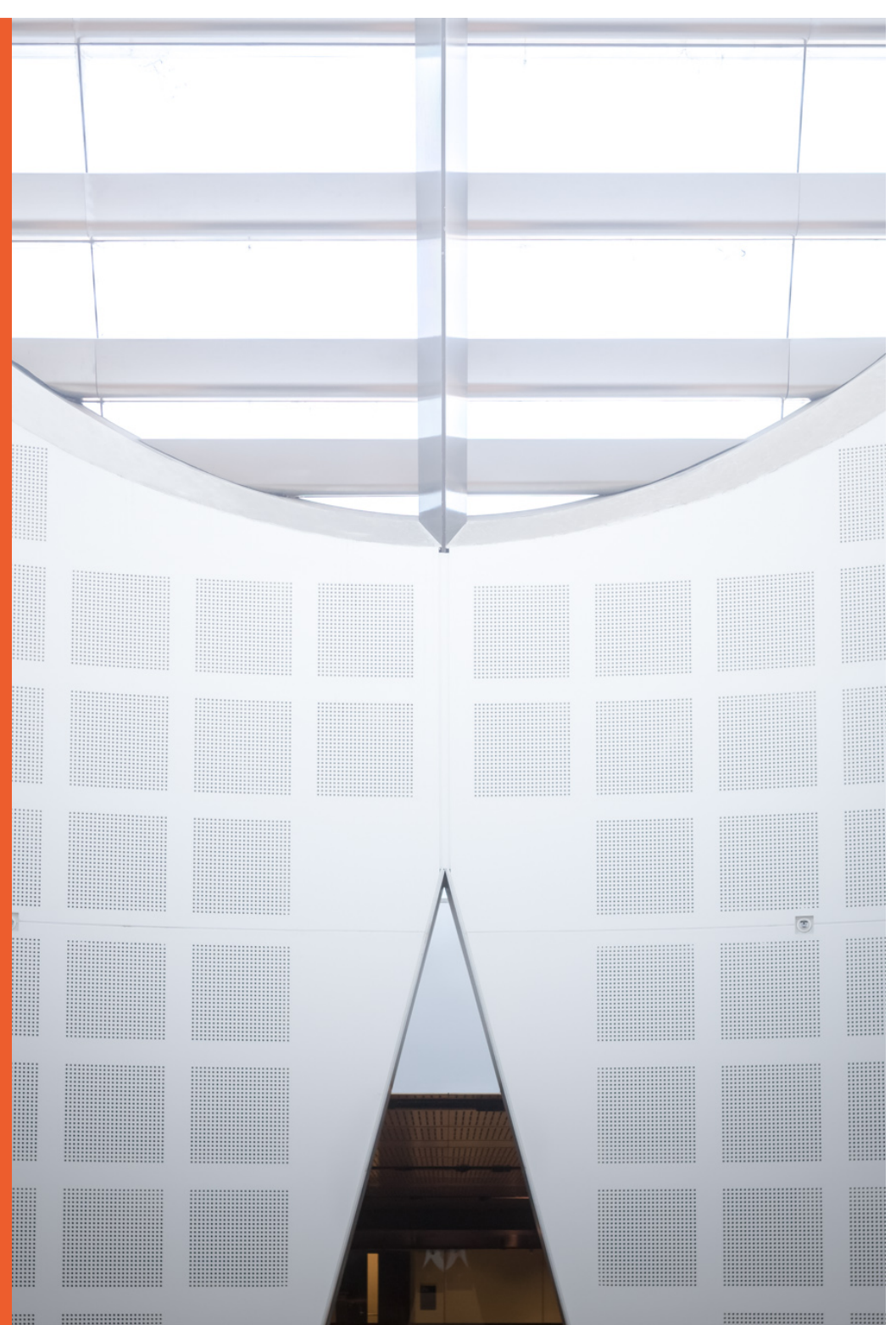
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Background

- Range of initiatives that allow access to medicines outside of traditional regulatory and reimbursement processes

  - Expedited review of regulatory and reimbursement applications

  - Conditional registration or subsidy

  - Dedicated funds to provide access to medicines that don't meet cost-effectiveness criteria

- Both benefits and risks

Discourse Surrounding Accelerated Access

– Benefits of latest treatments and terminally ill patients who have been saved by these

– Calls for patients to

  – "demand access to timely and affordable medicines"

  – advocate for the "right to try" experimental therapies

– Promises by politicians to

  – fund medicines rejected by health technology assessment bodies and

  – speed approval of promising new therapies

Aims and Research Questions

- Aim
  - To explore and critically analyse the discourses surrounding different forms of accelerated access

- Research questions
  - What arguments do stakeholders make, for or against, accelerated access
  - How do they construct these?
  - What, if any, rhetorical techniques do they use?

Methods: Choice of Case Studies

- Analysed published discourse on three examples/types of accelerated access

- Chosen because topics of public and policy debate
    - Cancer drugs fund
    - Managed entry and coverage with evidence development
    - Drugs for rare diseases

Methods: Identification of Published Material

- Cancer drugs funds and managed entry
  - Databases Google, Google Scholar and Factiva in September 2016
- Rare diseases
  - Publically-available submissions to the Australian government reviews of Orphan Drug Program and Life-Saving Drugs Program
- Inclusion criteria
  - Stakeholder views or experiences
  - Published in English between 2011 and 2016
- Process for selecting material
  - Most recent material first
  - Identified key characteristics
  - Moved onto the next piece if already had similar material

Methods: Data Analysis

- Structure of arguments analysed using Fairclough and Fairclough's framework for analysing political discourse
  - Values
  - Circumstances
  - Goals
  - Claim for action
  - Issues that aren't discussed

- Rhetorical techniques
  - Language and metaphor
  - Type of data presented
  - Logical fallacies

Methods: Data Analysis Cont'd

Title:

Description:

Stakeholder group:

Year:

Country/region:

Type of accelerated access:

Aspect	Description	Example
Empirical and social circumstances		
Values		
Goal		
Claim for action		
Issues that aren't discussed		
Techniques		

Results: Material Analysed

- Analysed 42 pieces
    - 14 for each case study
- Stakeholders represented include
    - Patients and patient advocacy groups (14)
    - Doctors (9)
    - Pharmaceutical companies (14)
    - Members of health technology assessment bodies (2)
    - Government ministers (2)
    - Multiple stakeholder groups (1)
- Material analysed related to processes in
    - Australia (24)
    - UK (15)
    - USA (3)

Results: Structure of Arguments

Circumstances	Inadequate access to therapies
Values	Respecting dignity, showing compassion, supporting patients, ensuring equity Governments being willing to spend adequate amounts on treatments Supporting the pharmaceutical industry
Goal	Accelerated access to medicines
Claim for action	Greater flexibility with regards to evidence and cost-effectiveness criteria
Issues that aren't discussed	Uncertainty surrounding safety, efficacy and cost-effectiveness Opportunity costs Sustainability of healthcare systems Other ways of improving access

Results: Rhetorical Techniques

– Personal stories from patients and arguments to pity

  – *Joe's cancer had been kept under control by a monthly injection and care at Leicester Royal Infirmary. However, in March he was told the tumours had started to grow again. The double blow came when specialists at London's Royal Free Hospital said the treatment they would have given him had been taken of the cancer drugs fund. To add to the couple's torment, the £56,000 treatment, which comprises four injections, is available in Wales, Scotland, Northern Ireland and across Europe.*

– Slippery slope arguments

  – *Disaster now looms on the horizon for some living with incurable breast cancer- the nightmare of having fewer available drugs could become a reality.*

Results: Rhetorical Techniques Cont'd

- – Appeal to the masses
  - – *In a recent survey commissioned by APA [Australian Pompe's Association] of a nationally representative sample of 1000 Australians of voting age… more than 85% would support government funding for medications costing $100 000 to $400 000 per year for a disease impacting 10 to 100 people.*

- – Appeal to precedent
  - – *The creation of the Cancer Drugs Fund was a huge step forward. Since its establishment, doctors have been able to offer their patients some of the best treatments available in the world. These treatments have greatly improved the quality of patients' lives, giving them precious extra months and even years of additional life with their families.*

Results: Rhetorical Techniques Cont'd

- Positive descriptions of new therapies
  - "Breakthrough", "innovative", "potential cure" and "wonder drug"
- Emotive language
  - Denial of treatment described as "cruel", a "death sentence" and a "time bomb"
  - Patients described as "angry", "anxious" and "fearful" of what could happen if they don't receive treatment
- Metaphors of war and battle
  - Patients are both "battling" illness and in a "battle" with regulators to access treatment

Policy Implications

- Emotive discourse surrounding accelerated access to medicines

  - Intense pressure to register and fund new medicines

  - despite uncertainty safety, efficacy and cost-effectiveness

- Options for policy-makers

  - Promote more balanced discourse?

  - Alternative means of access?

Questions?