Health Economic submissions

Regulation and Market Access 101

Thinking critically, acting practically

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Disclaimer

This presentation reflects my own views and does not reflect the views of any company or organization that I am or was affiliated with.

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Outline

- Access to medicines
- Evaluator's perspective
- Applicant's perspective
- Competencies / skills set
- Format of submissions
- Main components of submission
- PE models
- Costing studies
- Source of data
- Interpretation of clinical trials
- Concluding remarks

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Why have I been asked to address Health Economic Submissions?

communication and transparency

Standardization of process

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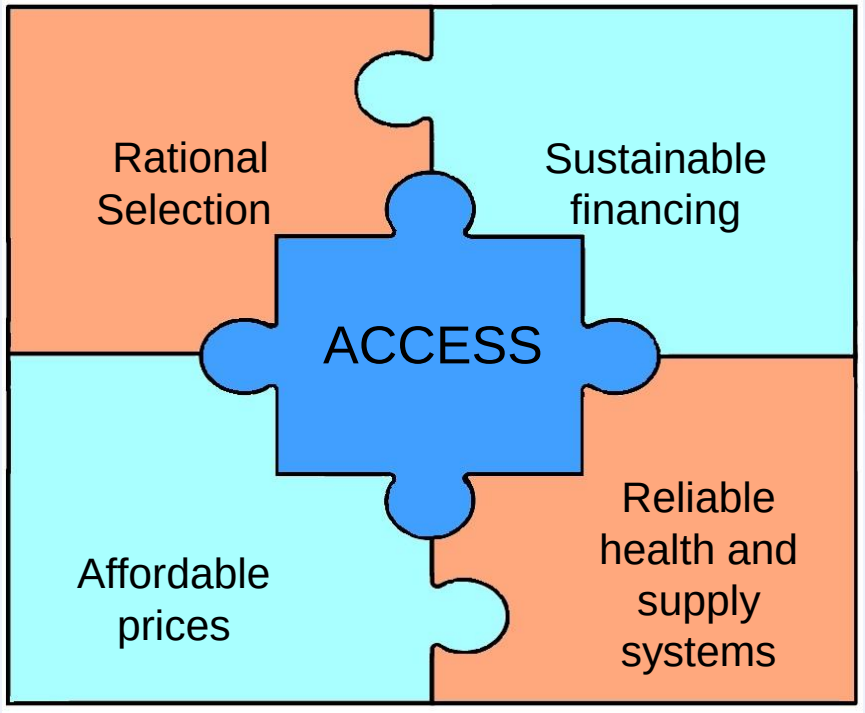
WHO framework for access to essential medicines

- National treatment guidelines
- National EML
- Rational use of EML



- Increased public funding
- Out-of-pocket spending
- Cost sharing with patients
- Donor assistance
- Donation of medicines

- Price information
- Price competition
- Bulk procurement
- Generic policies
- Equitable pricing
- Reduction or elimination of duties and taxes
- Local production of assured quality

- Health sector development
- Public-private-NGO mix
- Regulatory control
- Procurement co-operatives
- Traditional and complementary medicines

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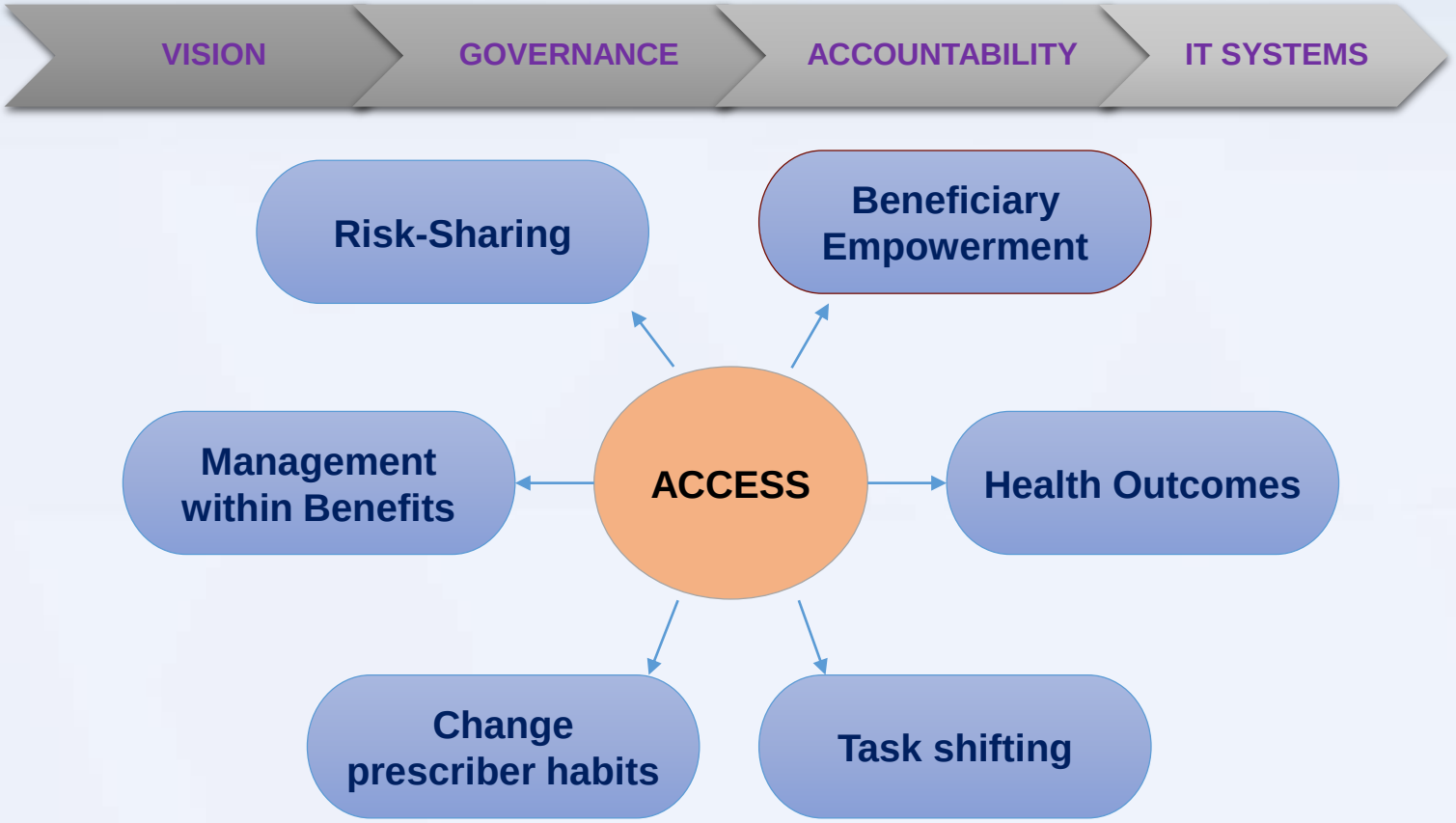

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Evaluator's perspective

- Quality of submissions
- Effective writing
- Lack of focus in submissions
- Executive summaries
- Ensure comprehensive submission
- Volume of material
- Misinterpretation of clinical trials
- Consistency in decision making - class review
- Lack comparative effectiveness data
- Interaction between role players /communication
- Certainty in decision-making

Applicant's perspective

- Standardization of process.
- Communication between funder and applicant.
- Understand therapeutic value of the product.
- Is the SEP reasonable?

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Competencies / skills set

Industry

- Pharmacoeconomics
- Health economics
- Clinical pharmacology
- Clinical trial evaluation
- Biostatistics
- Pharmaceutics

Personal journey

- Pharmacodynamics
- Pharmacokinetics
- Pharmacoeconmics
- Clinical trial evaluation
- Evidence-based medicine
- Clinical evaluation
- PK modelling
- Costing studies
- Health outcomes

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Format of submissions

- Submission templates
- PE guidelines

Main components of PE submission

- Clinical evaluation
- Pharmacoeconomic evaluation

PE models

- Use simple models as far as possible.
- Clear
- Transparent – understand workings, re-run
- Certainty of result – follow-through
- Confidence in decision making – correctness

Costing studies

- Minimal cost data
- Actual costs associated with an episode of care including costs of adverse events
- Sharing of cost data
- Simulations
- Time-motions study – public sector

Source of data

- Cost data
- Effectiveness data
- Managed care companies
- Win-win situation - governance and transparency
- Database of costs – private and public sector

Interpretation of clinical trials

Multiple Sclerosis and Related Disorders (2015) 4, 187–191

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/msard

REVIEW

Smoke and mirrors: Limited value of relative risk reductions for assessing the benefits of disease-modifying therapies for multiple sclerosis

Magd Zakaria*

Faculty of Medicine, Ain Shams University, 44 ElAhram street, Heliopolis, Cairo, Egypt

Received 29 January 2015; received in revised form 29 March 2015; accepted 31 March 2015

	Trial (1) Low	Trial (2) Inter	Trial (3) High
Risk (relapse) in Placebo	4%	40%	90%
Risk (relapse) in new medicine	2%	20%	60%
Relative Risk Reduction (RRR)	50%	50%	33%
NNT	50	5	3
Absolute Risk Reduction (ARR)	2%	20%	30%

A high RRR may result from a *clinically insignificant* change in the event rate if the event rate of the placebo is very low (trial 1)

Magd Zakaria, Multiple Scelerois and Related Disorders (2015),4,187-191

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Concluding remarks

- Standardize submissions to funders.
- Establish communication channels.
- Focus on rational use of medicines to reduce wastage and not on medicine price only.
- Need to establish sources for data.
- Consider the total cost of care or the cost per episode of care.
- Review dossiers before submission to the MCO.
- Conduct outcomes research for effectiveness data.
- Ensure proper interpretation of clinical trials.
- The workings of a PE model should be clear.