




*2017 Biotechnology
Entrepreneurship Boot Camp
Supplementary Session*

**Biopharmaceutical Pricing and
Access to Medicines**

Stephen M. Sammut

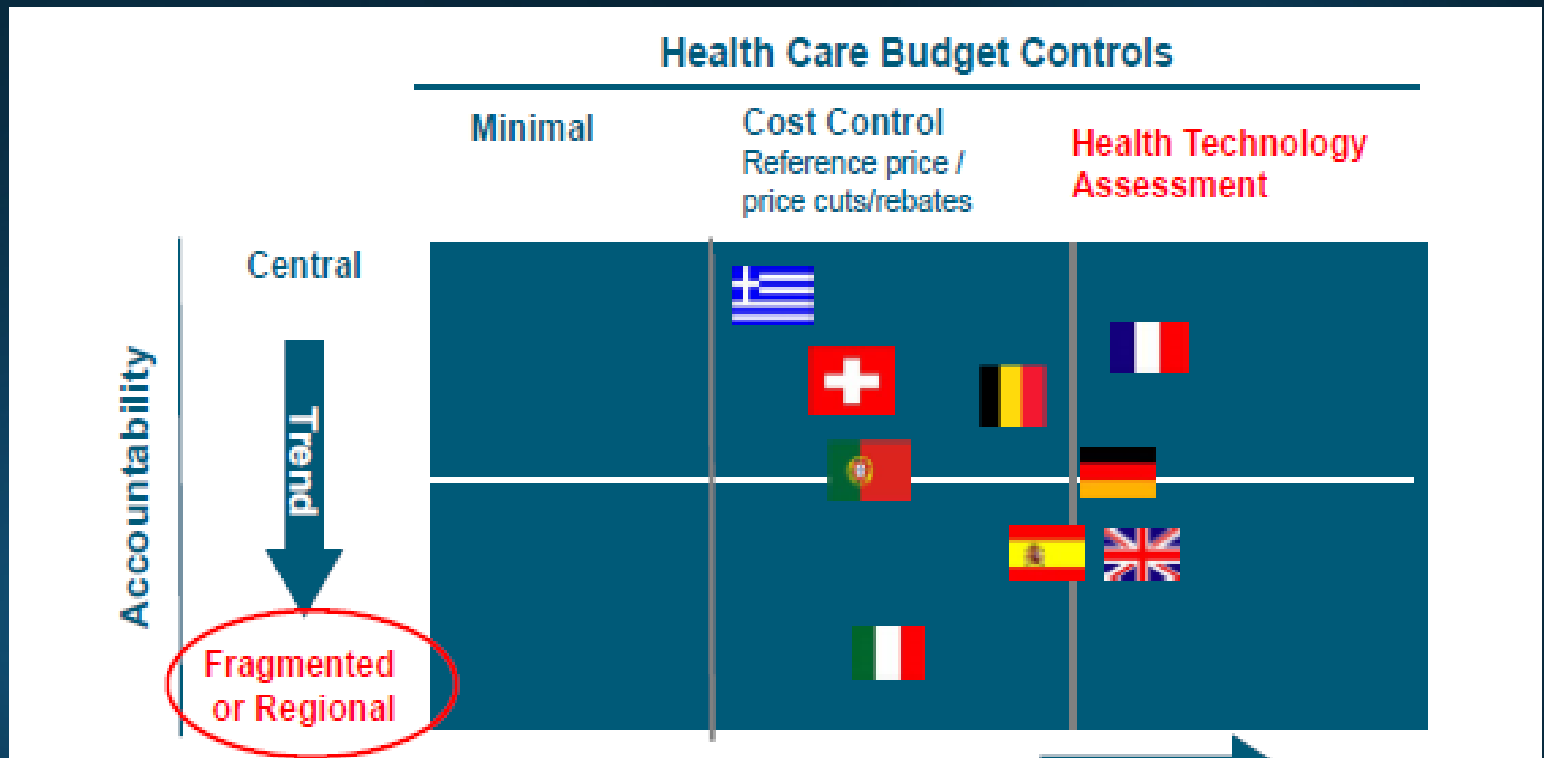
**Senior Fellow, Health Care Management
Wharton School, University of Pennsylvania**



Basic Concepts of Pharmaceutical Access

- “Access” represents the response of a pharmaceutical company to the regulatory, political and market challenges which determine how their products will meet patient needs
- Pricing is a function of access but is neither the sole factor or the market gatekeeper
- Pricing depends on R&D and manufacturing productivity, and the means through which the clinic can be reached
- Market Access relies on the lean strategy of the company aimed at the shortening time period of go-to-market model, from the stage of clinical trials to the process of reimbursement
- Access is the strategy of a company to adjust business processes in congruence with regulation and reimbursement.

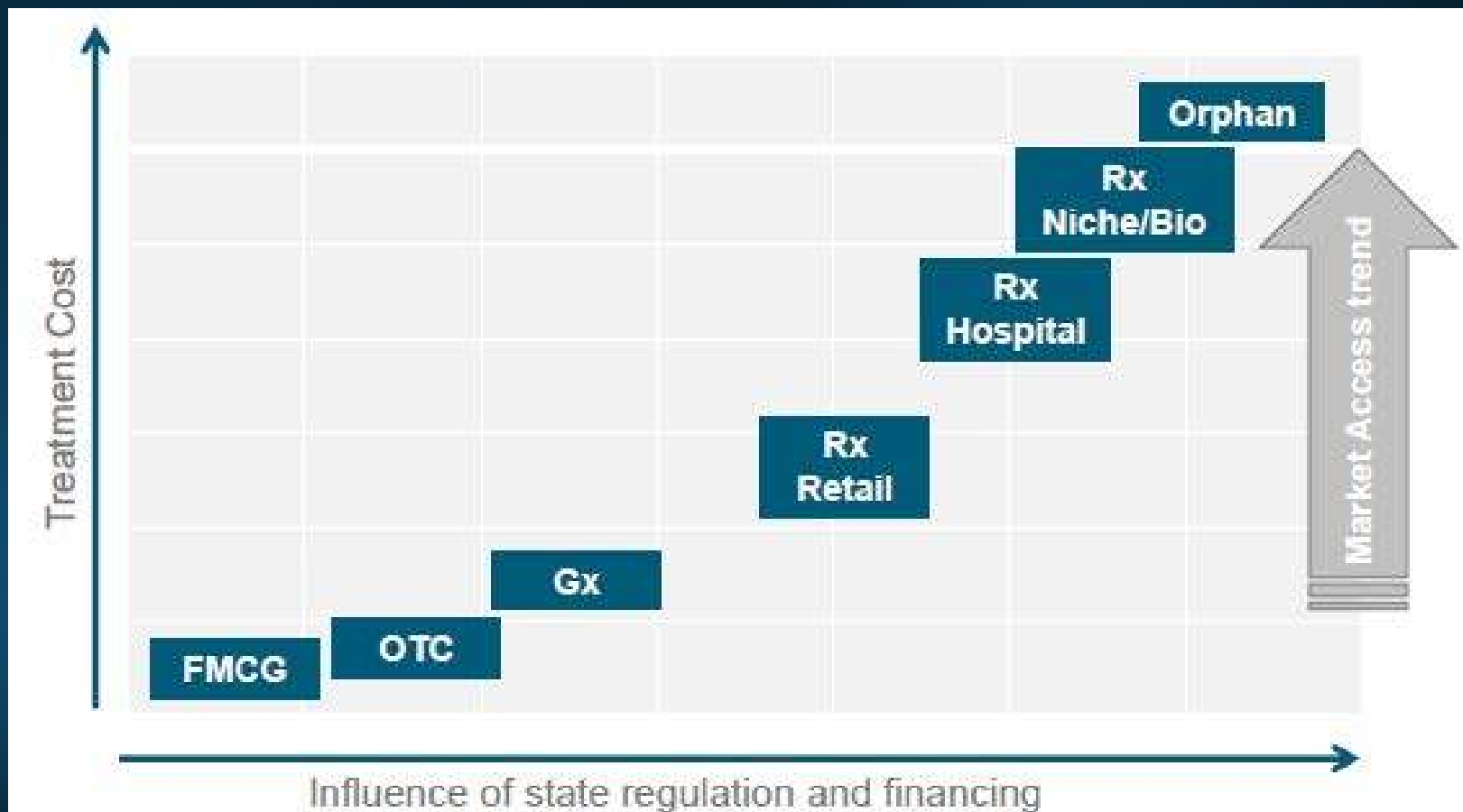
Access to products is core to business where health care cost containment and regional accountability are most advanced



TREND

- Payer decisions are more evidence based
- Health care decisions are delegated beyond physicians
- Acknowledge the local payer as the driver for access


Market Access as a Function of





Factors Influencing Access and Pricing

- Unmet needs of the health care system
- Clinical value of the new product
- Social value of the new product
- Economic value of the new product
- Product differentiation
- Availability of alternative pharmaceuticals or treatments
- Treatment time-line/ course of treatment
- Pharmaceutical form and mode of administration
- Promotional/educational channels
 - To physician
 - To patient/consumer
- Production venue (in some countries)




Integration of pharmaceutical products into the health care system

Stage	Key Activities
Phase II	Assessment of clinical potential
Phase III	Assessment of marketing potential
Registration	Integrated market access plan Pricing
Product listing/dispersion	Clinical protocols. Standards Formulary lists
Sales	Pricing negotiations Tender activity
Life Cycle Management	New indications New pharmaceutical forms/combinations



Key Imperatives for Access and Pricing

To secure optimal registration, pricing, reimbursement and listing in the shortest time possible both at launch and throughout the product life cycle

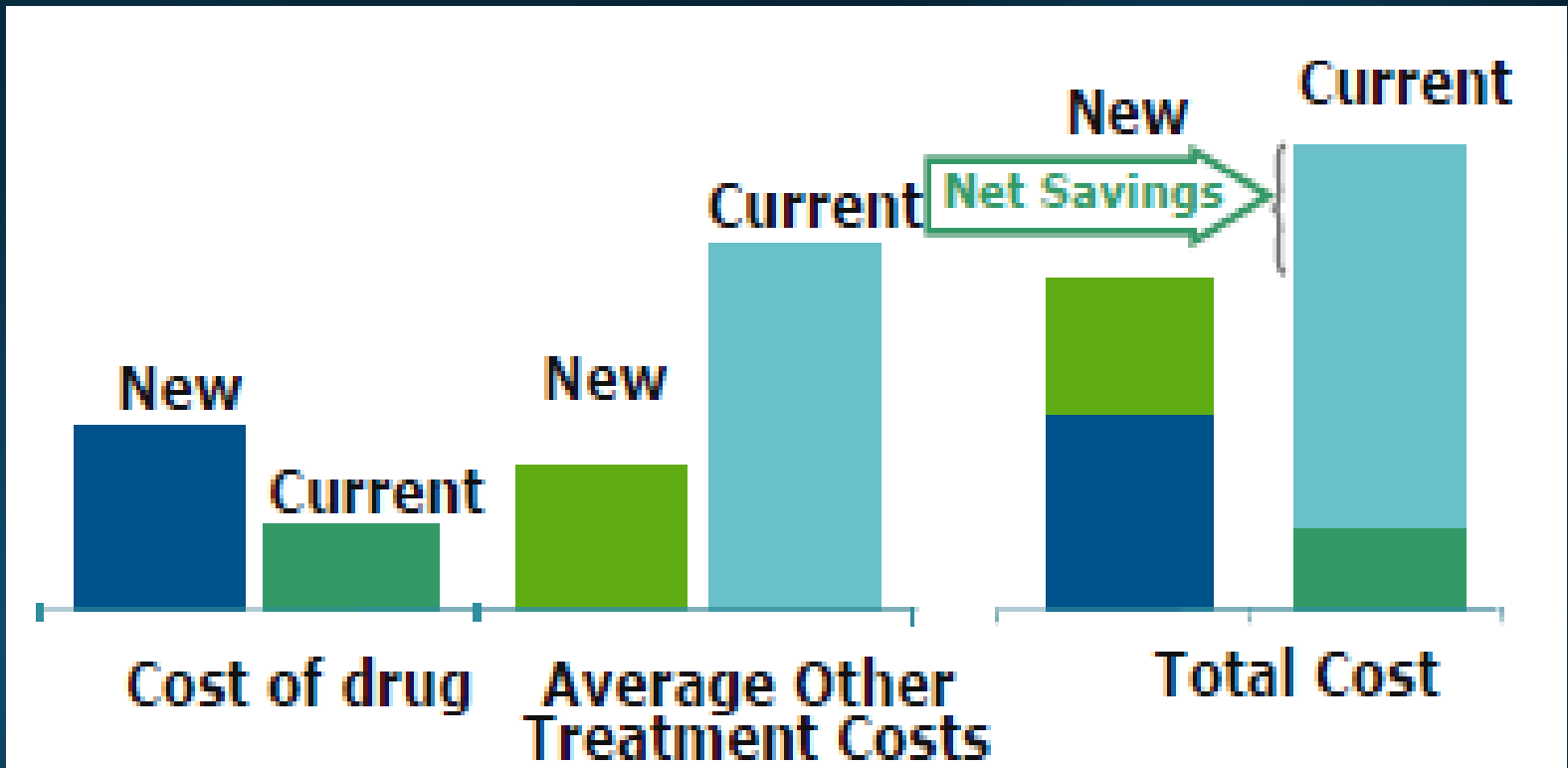
- 
- Stakeholder and customer identification and understanding
 - Obtain and maintain
 - Regulatory approval with best label
 - Target price
 - Reimbursement
 - Develop an evidence based, innovative value proposition that connects to the needs and expectations of stakeholders



Key pricing concepts

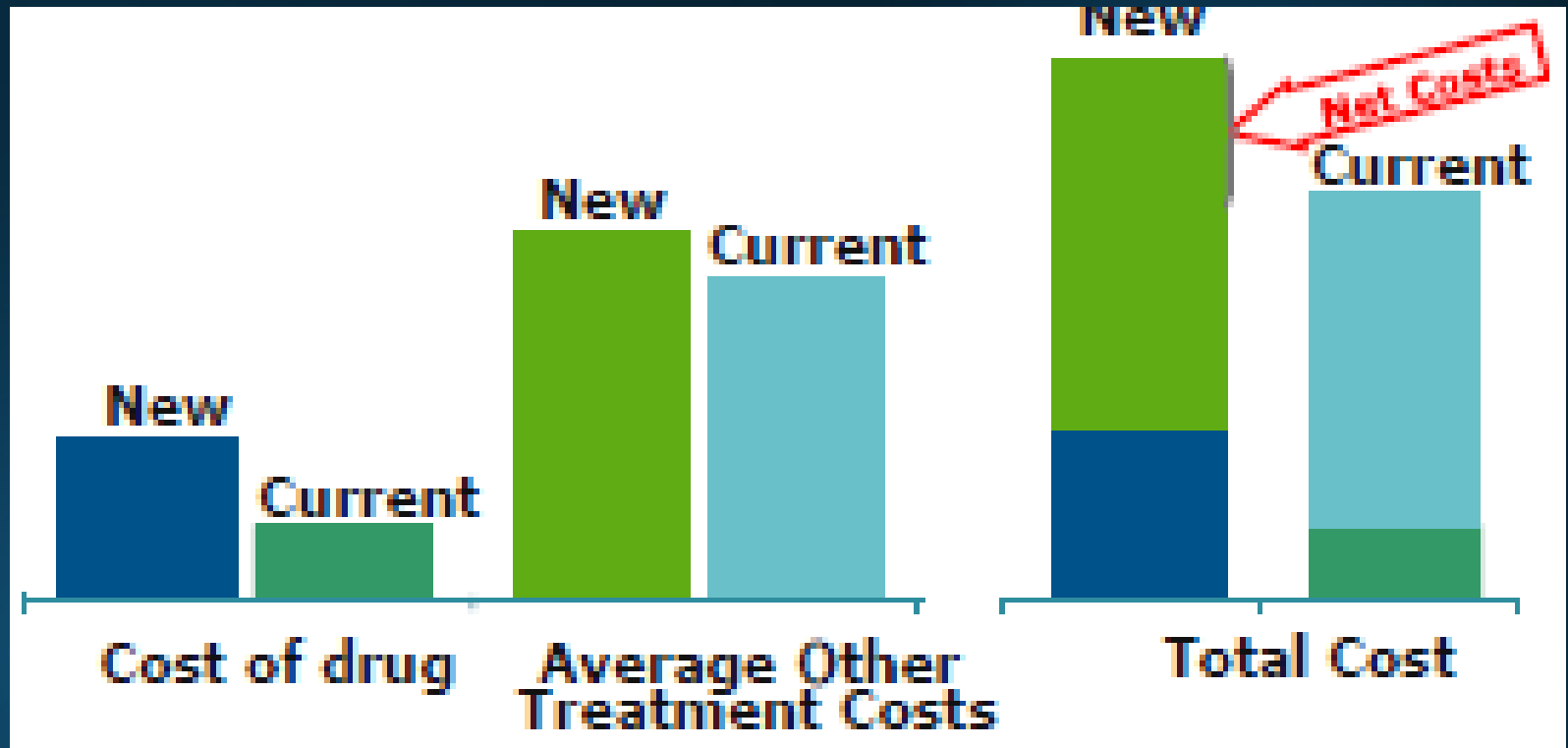
Cost-based pricing	Based on the marginal cost of production plus appropriate return on investment	Generic products
Competition-based pricing	Based on opportunity cost of using improved product over next best alternative	Original products under IP in highly competitive segments
Value-based pricing	Based on opportunity cost of perceived value for patients, payers, national economy and health system	Innovative pharmaceuticals in niche markets or high-cost of care environments (e.g., orphan diseases; oncology)

New medicine vs. current care: scenario 1



- Physicians
- Hospital/surgery
- Other medicines
- Tests

New medicine vs. current care: scenario 2




Physicians
Hospital/surgery
Other medicines
Tests

Health Economics Evaluation

The comparative analysis of alternative courses of action in terms of BOTH their costs and health consequences





Costs vs. Effects: the core of value proposition

- What is associated with this net cost ▲ in terms of ▲ benefits?
 - Lower toxicity?
 - More patients with better response to treatment
 - Prolonged duration of response
 - Increased survival
 - Increased quality of life
 - A cure
- Ratio: net cost ▲/benefits OR the CER (Cost Effectiveness Ratio) is the core element of value proposition from pharmaceutical company to payer.

The pricing and
reimbursement exercises
start . . .

. . . at product conception

