Beyond Price × Volume
The intricacies of budget impact analysis and managing pharmaceutical budget

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- Slides and recording will be shared after the session
Today’s Panellists

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Beyond Price x Volume
The intricacies of budget impact analysis and managing pharmaceutical budgets

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27 October 2022
Background

- Health care budgets, which tend to be set prospectively, set caps on spending within the healthcare sector to reduce financial risk for payers.
- Recent epidemiological trends and growth in pharmaceutical expenditure have raised concerns that the provision of safe and efficacious medicines may become unsustainable.
- In response, many countries have, among others, implemented aggressive cost-containment policies, including price controls, volume controls, budgeting, and market oriented policies in order to promote economic and fiscal sustainability.
- Budget setting is a key tool used in health financing by risk-averse payers to promote both economic and financial sustainability. However, the approaches taken by countries to achieve these objectives, particularly in the types of budgets employed, vary considerably across settings.
Key considerations for budget setting

1. What is the scope of the budget?
2. What is the length of the budget? How frequently is the budget revised?
3. How is the budget set?
4. What are the consequences for exceeding the budget?
5. Who is responsible for payback? Are there any exemptions for certain types of products or expenditure?

Key Message: The consequences of exceeding a budget must be clearly defined. Soft budgets without payback mechanisms are frequently exceeded.
Scope of Medicines Budgets

5 broad categories of medicines budgets:

1. Global budgets (E.g. UK, Greece, Portugal)
2. Regional budgets (E.g. Italy, Spain)
3. Therapeutic area budgets (E.g. UK cancer drugs fund)
4. Product-specific budgets (E.g. Price-Volume Agreements)
5. Prescribing budgets (fixed GP budgets in UK)

Key Message: Budgets are present at both the macro- and micro-levels of the pharmaceutical sector.
Mechanism for Setting Budgets

1. Drug spend linked to real GDP (E.g. Greece, Portugal)
2. Drug spend set based on historical figures, future PE growth linked to GDP growth (E.g. Spain)
3. Drug spend set at a fixed % of total health expenditure (E.g. Italy)
4. Drug spend set annually based on a range of criteria including GDP growth, public sector deficits, and other macro criteria (E.g. France)
5. Drug spend set based on historical figures, annual growth rate set at fixed % (E.g. UK PPRS)
### Mechanisms of budget setting - Country examples

<table>
<thead>
<tr>
<th>Countries</th>
<th>Description</th>
<th>Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Portugal</strong></td>
<td>Annual budget for all pharmaceutical expenditure linked to GDP (EAP 2011)</td>
<td>Pharmaceutical expenditure capped at 1.25% of GDP in 2012 and 1.0% of GDP in 2013.</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>Farmaindustria Protocolo (Implemented in 2015)</td>
<td>Growth in pharmaceutical expenditure linked to growth in GDP</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td>Global pharmaceutical expenditure budget linked to health expenditure (Implemented in 2002)</td>
<td>Fixed budget ceiling as a % of total health spend: Budget set at 13% of total health expenditure (changed to 13.1% in 2012 and 11.4% in 2013)</td>
</tr>
<tr>
<td><strong>France</strong></td>
<td>Annual budget for pharmaceuticals set prospectively by French Parliament (Implemented in 2002).</td>
<td>Set by parliament based on GDP growth, public sector deficits, and other macro criteria.</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td>Voluntary Scheme for Branded Medicines Pricing and Access (VPAS, UK), 2019-2023</td>
<td>Allowed annual growth in pharmaceutical expenditure id 2% in anyone year; repayment percentage (depends on the difference between allowed growth and forecast growth the the NHS of branded medicines (2019: 9.6% of eligible spend); 36 months exemption for new active substances and improved exemption for smaller companies</td>
</tr>
</tbody>
</table>

**Key Message:** Although it is not linked to drivers of pharmaceutical expenditure, GDP is a determining factor in setting pharmaceutical expenditure in several countries.
## A Taxonomy of Pharmaceutical Budgets

<table>
<thead>
<tr>
<th>Type of Budget</th>
<th>Global</th>
<th>Regional</th>
<th>Disease Specific</th>
<th>Product Specific</th>
<th>Prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Cap on annual national pharmaceutical expenditure.</td>
<td>Cap on annual regional pharmaceutical expenditure.</td>
<td>Fixed budget for medicines that treat a specific diseases or group of diseases</td>
<td>Fixed budget for the use of a medicine within a specified indication</td>
<td>Ex ante cap assigned to physicians for prescribing medicines</td>
</tr>
</tbody>
</table>
| **Modalities** | 1. Linked to GDP  
2. Linked to GDP growth  
3. Linked to health expenditure  
4. Fixed rate of growth  
5. Set annually based on macro criteria | 1. Linked to national pharmaceutical expenditure. | 1. Specific disease (e.g. UK Cancer Drugs Fund)  
2. Group of diseases (e.g. Scotland New Medicines Fund) | 1. Price-volume agreement  
2. Fixed-cost per patient | 1. Ex ante annual cap  
2. Capitation |
| **Implementation** | Payback of excess expenditure by manufacturers based on market share. Optional exemptions for innovative medicines, generics or orphan products | Part of national budget framework, regions liable to payback a portion of budget excess. | Special review process to access funds. Target budget set but typically not enforced. | Negotiated as part of a managed entry agreement for the reimbursement of a new drug. Price cut or payback if target exceeded | Audits and payback for exceeding annual cap or positive incentives for meeting cap. Capitation payments cover all physician costs including salary. Excessive expenditure results in reduced salary. |
| **Objectives** | Cost-containment and affordability (1&2)  
Macro-economic efficiency (3&5)  
Cost-containment and industrial policy (4) | Equitable access and rational use (1) | Access to high cost medicines (1&2) | Limit budget impact of a product (1)  
Improve cost-effectiveness of a product (2) | Rational use and appropriate prescribing (1&2) |

# Advantages and Disadvantages of Pharmaceutical Budget Caps

<table>
<thead>
<tr>
<th>Type of Scheme</th>
<th>Promotes cost-containment</th>
<th>Minimizes financial risk</th>
<th>Straightforward to implement</th>
<th>Avoids spill-over effects (e.g. price cuts)</th>
<th>Promotes macroeconomic efficiency</th>
<th>Promotes microeconomic efficiency / rational use</th>
<th>Promotes access to innovative medicines</th>
<th>Promotes equitable access to medicines</th>
<th>Promotes quality of medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Budgets linked to GDP</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>✗</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Global budgets linked to health expenditure</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>✗</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Global budgets with fixed annual growth</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>✓</td>
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<td>~</td>
</tr>
<tr>
<td>Global budgets set based on macro criteria</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
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<td>~</td>
</tr>
<tr>
<td>Regional Budgets</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
<td>~</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Disease-specific budgets</td>
<td>✗</td>
<td>✗</td>
<td>~</td>
<td>~</td>
<td>~</td>
<td>X</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
</tr>
<tr>
<td>Product specific PVAs</td>
<td>✓</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>✓</td>
<td>✗</td>
<td>~</td>
</tr>
<tr>
<td>Product specific fixed-cost per patient</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>✓</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Prescribing budgets annual ex-ante cap</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>✓</td>
<td>X</td>
<td>✗</td>
<td>~</td>
</tr>
<tr>
<td>Prescribing budget capitation</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>~</td>
<td>✗</td>
<td>✗</td>
<td>~</td>
</tr>
</tbody>
</table>

✓ Positive effect  ❌ Negative effect  ~ No impact

Trade-offs between macroeconomic efficiency and microeconomic efficiency in the use of pharmaceutical budgets

Prioritizes macroeconomic efficiency/financial risk minimisation

- **Portugal**: ↑ budget linked to GDP, ↑ price-volume agreements, ~ target prescribing budget
- **Greece**: ↑ budget linked to GDP, ~ target prescribing budget
- **France**: ↑ budget set based on macro-criteria, ↑ price-volume agreements, ~ target prescribing budget
- **Spain**: ↑ budget linked to GDP, ↑ price-volume agreements, → regional budget, ~ target prescribing budget
- **Italy**: ↑ budget linked to health expenditure, ↑ price-volume agreements, → regional budget, ↓ disease specific budget
- **Germany**: → hard prescribing budget
- **UK**: ~ annual fixed growth budget, ↓ disease specific budget, → capitation payments
- **Greece**: ↑ budget linked to GDP, ~ target prescribing budget
- **Spain**: ↑ budget linked to GDP, ↑ price-volume agreements, → regional budget, ~ target prescribing budget
- **France**: ↑ budget set based on macro-criteria, ↑ price-volume agreements, ~ target prescribing budget
- **Italy**: ↑ budget linked to health expenditure, ↑ price-volume agreements, → regional budget, ↓ disease specific budget
- **Germany**: → hard prescribing budget
- **UK**: ~ annual fixed growth budget, ↓ disease specific budget, → capitation payments

Summary

- Pharmaceutical budgets are frequently used as a means of cost-containment.

- GDP-linked budgets neither address drivers of expenditure or promote efficiency.

- Silo budgeting reduces flexibility in allocating health resources optimally.

- Soft budgets lack enforcement and are frequently overrun.

- Complimentary policy measures are needed to promote health system objectives.
Pharmaceutical budget impact assessment in Egypt

presented by:

DR. Asmaa Saad Abourawash
Pharmacoeconomics Unit Head,
Egyptian drug authority
Presentation Outline:

1. The need for Budget impact analysis in Egypt
2. Past and Current Reforms in Egyptian HC system
3. Hepatitis C success story
4. Challenges and potentials in Egypt
Need for budget impact assessment

- Current health care expenditure per capita in 2019 is 149$ and that representing a percentage of 4.74% of GDP
- Government health expenditure represents around 28% of the current healthcare expenditure.
- Government expenditure on health represents 4.6% of the general government expenditure.
- Limited budget with many consequences:
  - Inequalities in access to care.
  - Suboptimal decisions due to limited resources.
  - Inefficiencies in the whole healthcare sector.
  - Patient harm.

The need for HTA adoption has been emerged for better allocation of those limited resources.

Based Primarily on: Cost-effectiveness & Budget impact analysis
Past reform
Before 2019

Ministry of Health

NODCAR
Central Administration of Pharmaceutical Affairs
MOH hospitals
Health Insurance
Other Governmental Hospitals
Private HC Sector

For: Drugs, MD, others
Marketing Authorization, PV
Inspection, licensing

Pricing
Pharmacoeconomics

Separate Tender
Separate Tender in Each Hospital

MOH Tender

Inform
Current Reforms,

Ministry of Health

- NODCAR
- NORCB

**NODCAR**
- QC for drugs and biologics
- Clinical Trials Authorization & Audit

**NORCB**
- Pricing
- Pharmacoeconomics

Central Administration of Pharmaceutical Affairs
- For: Drugs, MD, others
- Marketing Authorization, PV
- Inspection, licensing

MOH hospitals
- Health Insurance
- Other Governmental Hospitals

**Unified Procurement Authority (UPA) & HTA**

**Universal health insurance (UHIA)**

Egyptian Drug Authority

Pharmacoeconomics unit with a New Sound
Egypt's HCV infection prevalence of 7% among adults was among the highest in the world and accounted for 7.6% of the country's mortality.

In late 2018, the government launched the 100 Million Seha (100 Million Healthy Lives) campaign. The campaign aimed to eliminate HCV as a public health threat.

It included free voluntary HCV screening to all residents of Egypt aged 18 years and older, or about 62 million people, and offered free treatment for confirmed cases.

Nearly 50 million Egyptians and 36,000 foreign residents were screened for HCV. Of those, 2.2 million individuals were seropositive, indicating HCV exposure or chronic infection, and referred for confirmatory testing. Of those referrals, 1.6 million patients had confirmed chronic HCV infection.

Testing and treatment were fully funded by the state, irrespective of one's financial ability or insurance coverage. Of all patients tested, 58% were covered by the NCCVH, 24% by the Egyptian Health Insurance Organization, and 15% paid out-of-pocket to secure brand name direct-acting antiviral drug combinations.
Hep C, 100 Million Seha

➢ In December 2013, the panorama of HCV treatment changed dramatically when the U.S. Food and Drug Administration approved sofosbuvir, a new class of HCV direct-acting antiviral drug.

➢ Sofosbuvir in combination with other antivirals offered up to a 90–95% sustained virologic response, or cure rate, using a simple and well-tolerated 12-week oral regimen. However, the retail price of this treatment was US$84,000 per individual case.

➢ Gilead, the pharmaceutical company that owned the patent for sofosbuvir, applied for a proprietary license in Egypt. The application was initially rejected, forcing the company to enter negotiations with the Egyptian government. These negotiations resulted in a voluntary licensing agreement in March of 2014. Sofosbuvir would be sold to the Egyptian government at a 99% discount, or US$900 per treatment course.

➢ Eventually, sofosbuvir was licensed to several Egyptian pharmaceutical companies. Between 2015 and 2018, it cost just US$54 for the typical 12-week treatment course in 2018.

➢ Between 2014 and 2020, Egypt screened more than 50 million and treated 4 million residents for chronic HCV, with the goal of eliminating HCV as a public health threat.
Lessons learnt

➢ Four key elements led to the success of this elimination program:

1. a reliable epidemiologic surveillance to quantify and monitor public health threats;
2. inclusive care that reached all sectors of society;
3. political commitment to public health through increased health care spending and a comprehensive long-term national control strategy; and
4. innovative scientific research and use of information technology

➢ Cost effectiveness study was conducted and yielded the discount percentage of sofosbuvir compared to peg interferon/ribavirin, and then budget impact analysis model based on the prevalence data estimated the budget impact for the treatment protocol.

➢ As proofed from hep C eradication story, “mass purchasing can reduce cost” and this is an important element in managed entry agreements disciplines.
Challenges for BIA in Egypt

- One of the main six key elements requiring inputs for the modelling framework of a BIA is the Size and characteristics of affected population; This process requires rates such as the prevalence of the condition, the proportion of patients with a particular severity or usage pattern, and other relevant features for the health condition and technologies being examined.

- Change in prevalence over the time horizon of the model because of new incident cases and people leaving the population through death or other changes in disease progression must be applied over time to ensure that the size of the population continues to reflect the prevalence with the current and new technologies.

- For Egypt, The main challenge as in many other countries is the absence of local epidemiological data of the accurate estimates of the population size, which in certain situations lead to exceeding the budget and unsustainability of the system in absence of well designed priori pay back mechanisms.

ex. Spinal muscular atrophy national initiatives program
After launching the initiative based on BIA using uncertain size of population, no. of diagnosed cases increased significantly and huge budget burden occurred and finally termination of program.
challenges

➢ Recent growth in pharmaceutical expenditure with introduction of innovative targeted therapies in very critical disease areas added a huge burden on the budget;
   o cost containment strategies with shifting to generic versions for achieving budget savings? Will it be better for patients QOL than doing nothing?
   o What about guaranteeing efficacy and safety in real world setting specially for disease areas with short lifespan?
   o The consequences of wrong decisions??

➢ Proper understanding of BIA outcomes from budget holders level and what variables it depends on for estimating the impact, and how any change in inputs will alter the impact;
   o building capacities workshops in progress now at stakeholders and modelers level
   o The capacity in Egypt who oriented with BIA conduction around 20 personnel.
Pharmacoeconomics unit with a New Sound

Potentials in Egypt

➢ Unifying the fragmented payer system into unified payer represented in UHIA will add value of fund pooling and more flexible budget correctly allocated.

➢ Establishing Registry for patients under the umbrella of UHIA will allow better estimation of prevalence data

➢ Society awareness and shifting towards introducing HTA applications in pricing and reimbursement setting

➢ Establishment of Egyptian association of health economics in 2021 as an attempt to acting on challenges together and paving the way for better HTA integration in healthcare system.

➢ Launching presidential initiatives in some disease areas; ex. Breast cancer screening campaigns of women aged above 25 years and enrollment of diagnosed cases in management protocols designed based on clinical and economic evaluation assessments(CEA&BIA)
Discussion time
Forecasting drug utilization and expenditure: ten years of experience in Stockholm

Love Linnér
Public Healthcare Services Committee
Region Stockholm
Sweden
Region Stockholm

- 2.4 million inhabitants
- Regional council – political assembly overseeing and funding public healthcare and transport
- Pricing and reimbursement decisions by national agencies
Yearly pharmaceutical budget

- Prescribed medicines (740 million €)
- Medicines administered by HCP (240 million €)

<table>
<thead>
<tr>
<th>Costs 2022 (m €)</th>
<th>Hospitals (primarily public owned)</th>
<th>Primary care</th>
<th>Specialised somatic care</th>
<th>Psychiatry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed:</td>
<td>250 47 32 19 2</td>
<td>150</td>
<td>195</td>
<td>45</td>
</tr>
<tr>
<td>Administered:</td>
<td>140 21 12 12 9</td>
<td>3</td>
<td>38</td>
<td>1</td>
</tr>
<tr>
<td>Primary cost groups:</td>
<td>haematology oncology heritable-disorders HIV</td>
<td>HIV oncology reumatology eyes IBD diabetes</td>
<td>oncology haematology IBD</td>
<td>eyes cardiovascular diabetes asthma pain skin</td>
</tr>
</tbody>
</table>
Forecasting drug utilization and expenditure: ten years of experience in Stockholm

Love Linnér\textsuperscript{1}, Irene Eriksson\textsuperscript{1,2*}, Marie Persson\textsuperscript{1} and Björn Wettermark\textsuperscript{1,2}

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\textsuperscript{2}Department of Clinical Sciences, Interventional and Surgical Sciences, Karolinska Institutet, Stockholm, Sweden

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Forecasting model (2007-2018)

- Medicines divided into therapeutic groups (ATC2/3)
- Previous drugs utilization for each group informs crude prediction for current and next year
- Predictions adjusted for factors likely to affect future expenditure
  - Patent expiries, new introductions, new indications, updated guidelines
- Predictions discussed with clinical experts in regional Drug and Therapeutics Committee and adjusted
- Forecast performed Q2 year 1. Horizon: year 1 (Q2-Q4) and year 2

Precision of forecast over time

- Percent change from previous year
- Same year forecast (Q2-Q4 of analysis year), Previous year forecast (year after analysis)
- Regression analysis: higher precision for same year forecast (n.s.). No change in precision over time.
Precision of forecast in selected therapeutic groups (2010 – 2018)
Precision of forecast for therapeutic groups 2010-2018
- Forecasted change in expenditure compared to actual change in expenditure (million SEK)
- Same year forecast significantly higher precision
Forecasting model (2019-2022)

- Medicines divided into more specific therapeutic groups (distribution & clinical)
- Predictions via software package (R/forecast*) for each substance per quarter
- Predictions adjusted for factors likely to affect future expenditure
  - Patent expiries, new introductions, new indications, updated guidelines
- Predictions discussed with clinical experts in regional Drug and Therapeutics Committee and adjusted
- Forecast finalized Q4 year 1. Horizon: year 1 (Q4) and year 2

Precision of forecast over time 2008-2021

- Percent change from previous year
- Regression analysis: No change in precision over time.
Precision of forecast for therapeutic groups

- Forecasted change in expenditure compared to actual change in expenditure
- Previous year forecast 2020-2022 significantly higher precision relative 2014-2018
Conclusions:

• Forecasts of pharmaceutical expenditure benefits greatly from short horizons (i.e. too many unknown outcomes of decisions with high impact for forecasts spanning several years)

• Forecasts for clinically relevant therapeutic groups allows for specific budgets to healthcare providers with different profiles

Thanks to:

• Björn Wettermark, Professor of pharmacoepidemiology, Uppsala Universitet
• Irene Eriksson, PhD, Uppsala Universitet
• Marie Persson, PhD, Region Stockholm

Contact: Love.Linner@regionstockholm.se
Panel discussion
Different methodologies (e.g. global/macro-level budgeting, disease-specific budget, product-specific budget) and budgeting process (e.g. setting fixed vs indicative budgets) have different purposes, strengths and weaknesses.

How should policy makers pick the ‘right’ method(s) and best consider the information from budget impact analysis when assessing and allocating budgets?
In what way could the "cost-effective but unaffordable" paradox be reconciled (or not), conceptually and pragmatically, through budget impact analysis?
Budget impact analysis often has a narrow focus on estimating the overall budget impacts on government expenditure, rather than impacts on different stakeholders along the supply and distribution chain.

In your view, to what extent could/should budget impact analysis examine the distribution of cost burden on different stakeholders? And what would be required to achieve this?
In countries where the private insurance/sector plays a significant role on the provision of medicines/health services, **cost shifting due to budget constraints** could happen.

To what extent could **budget planning** (e.g. coverage, level of statutory coverage, copayment policies) **avoid such phenomenon**, and in what way?
Much emphasis has been placed on developing capacity in undertaking cost-effectiveness analysis, but budget impact analysis could be at least as technically challenging.

In your views, what are the main capacity building needs for developing budget impact analysis in countries and for relevant stakeholders?
Q&A with the audience
Upcoming webinar

- Sharing prescription costs: country policies on pharmaceutical co-payments and their implications


https://www.who.int/news-room/articles-detail/call-for-experts--who-technical-advisory-group-on-pricing-policies-for-medicines

The deadline is 25 November 2022.