Governance and mechanisms to manage transparency in medicines’ access and pricing reform

Fair Pricing Webinar, June 2022
Achieving UHC requires people having access to safe, effective, quality, and affordable essential medicines and vaccines for all.

3.8 Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.

16 Promote peaceful and inclusive societies for sustainable development, provide access to justice for all, and build effective, accountable and inclusive institutions at all levels.
Potential vulnerabilities in the pharmaceutical system

Transparency and accountability to improve access to medicines

Key WHO transparency and pricing resources

Pharmaceutical System
Transparency and Accountability
Assessment Tool

Good Governance for Medicines
Progressing access in the SDG era

https://apps.who.int/iris/handle/10665/275370

https://www.who.int/publications/m/item/wHA72.8

https://www.who.int/publications/i/item/9789240011878
Today's discussion
Governance and mechanisms to manage transparency in medicines' access and pricing reform

Discussants:

Barbara Mintzes  University of Sydney, Australia
Inneke Van de Vijver  RIZIV-INAMI, Belgium
Denis Kibira  MeTA-Uganda

Key questions:

• What mechanisms or structures could countries use to promote transparency in policy reform?
• What ‘checks and balances' could national authorities establish to bolster governance in the pharmaceutical sector?
• Is transparency alone sufficient to enable accountability? What else is needed?
A Taster....
Assessing and managing relationships between the pharmaceutical industry, health professionals & patient groups

A/Prof Barbara Mintzes
School of Pharmacy & Charles Perkins Centre
University of Sydney
WHO Fair Pricing Webinar, June 8, 2022
Financial Disclosure

- No pharmaceutical or device industry funding
- Expert witness for Health Canada, lawsuit on marketing of an unapproved drug

Funding for our team’s work on conflicts of interest

- NHMRC
- Australia-Korea Foundation
- Yonsei University - University of Sydney Partnership grant
Background and focus

- Financial conflicts of interest (COI) are ubiquitous in medicine.
- COI are associated with a risk of research bias, and suboptimal clinical care and patient representation.
- Transparency databases are a window on the extent and effects of influence.
- Limited management to date

http://www.cbc.ca/news/health/doctors-pharmaceutical-funding-1.4164625
“A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”

- US Institute of Medicine, April 2009
Sunshine legislation

The legislation “sheds light on all of these hidden payments and obscured interests through the best disinfectant of all: sunshine.”

US Senator Chuck Grassley
The facts about Open Payments data

Total US Dollar Value | Total Records Published
----------------------|------------------------
$59.52 Billion        | 78.52 Million

Payments by Type

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<th>$ General Payments</th>
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https://openpaymentsdata.cms.gov/summary
Accessibility and quality of drug company disclosures of payments to healthcare professionals and organisations in 37 countries: a European policy review

Piotr Ozieranski, Luc Martinon, Pierre-Alain Jachiet, Shai Mulinari

ABSTRACT

Objectives To examine the accessibility and quality of drug company payment data in Europe.

Design Comparative policy review of payment data in countries with different regulatory approaches to disclosure.

Setting 37 European countries.

Participants European Federation of Pharmaceutical Industries and Associations, its trade group and their drug company members; eurofordsdocs.eu, an independent database integrating payments disclosed by companies and trade groups; regulatory bodies overseeing payments.

Strengths and limitations of this study

- We investigate the quality and accessibility of drug company payment disclosure data in 37 European countries.
- We use a set of measures relevant for countries with industry self-regulation, public regulation and a combination of the two.
- We present our results as a ‘heat map’, showing the least and most problematic aspects of payment data accessibility and quality.
Of 37 countries, most rely on industry self-regulation.

Table 2  Approaches to regulating payment disclosure in European countries

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n=37  n=30  n=11  n=4

Ozieranski et al. 2021
Drawbacks of Industry Self-regulatory approaches

- “Opt-out” consent clauses
- Omitted payment types
- Data Access
- Data useability
- Only member companies

*Image: J Gauntner sake-world, 2012*
An example:

Australian Transparency Reports

• Since 2007, all industry-sponsored events reported – unique globally
• Largely buried in plain sight until 2018
Industry sponsored “educational” events for health professionals

Australia Oct 2011 to September 2015

• 116,845 events or 608/ week

• Food and drink at over 90%

• Total cost: AUD $286 million

Individual payment reports, 2015 on
But disappearing data

Industry-sponsored food and drink
Does this matter?

Trials (n=120); 56 (47%) with Australian authors with undeclared COI

Research on Industry Payments versus Self-report

Flood et al. JGIM 2022
Australian Patient Organisations
$23.6 million, 2013 to 2016

52% (95% CI 44% to 61%) with listed funding disclosed it.
- Lau et al. 2019
In conclusion

– Transparency reports a window, not a disinfectant
– Industry self-regulatory systems often flawed
– Open Payments – current “best practice”

Management – little to date
– Sweden – ban on conference payments
– France – no meals over €60
– Patient groups?
Questions or comments?

Barbara.Mintzes@Sydney.edu.au
Beneluxa’s experience on "setting a willingness (likeliness) to pay”:

A payer's perspective on facilitating transparency towards the public/industry
The role of Multi-stakeholder groups in improving access to medicines: The MeTA experience

Denis Kibira
National Coordinator
MeTA-Uganda
Multi-stakeholder Platforms (MSPs)

- MSPs bring together representatives of different interest groups to discuss shared challenges, opportunities, policy actions and advocacy strategies (Warner 2005)
Amplifying community voice

- Household level
- Community level
- National level
Outline

- What is MeTA?
- MeTA Priorities
- Strategy
- Structure & Operations
- Achievements
- Challenges and opportunities
What is MeTA?

- DFID-led initiative launched in 2008 to improve access to medicines through multi-stakeholder participation.
- Improve health outcomes through increased transparency in health commodities supply chain.
- Catalyst/Driver for change
- Was initiated in 7 countries: Ghana, Uganda, Zambia, Jordan, Kyrgyzstan, Philippines, Peru.
MeTA in principle

“Every voice is important, every voice counts”
Key drivers

- Country ownership
- Stewardship by govt - the Ministry of Health
- CSO secretariats
- Research agenda
- CSO capacity building
Key MeTA Priorities

- **Availability** of and **access** to medicines
- **Cost** of medicines to consumers involving amongst others the options of pricing policies
- **Quality** of medicines, involving quality standards and registration
- **Rational use of medicines** by prescribers and consumers
MeTA Strategy

Evidence

• Provide tools & training for measurement of a basket of SRH commodities.

Capacity

• Build regional capacity in collection of evidence.
• CSO training on SRHC policy advocacy.

Structure & Operations

- **MeTA Council**: governing body of core institutions in the medicine sector; from Gov’t, Private sector and CSOs.

- **Secretariat**: Hosted by CSO with 3 members; MoH, Academia, Private sector.
  - Oversees implementation of activities.

- **National Stakeholder Forum**: wide stakeholder group—meets annually to exchange information.

- The structure may be different depending on country context and priorities.
Achievements in Uganda

Multi-stakeholder working:

- Initiated MoH collaboration with private sector and CSOs in policy dialogue- 1st all inclusive stakeholder platform
- Involvement in medicine policy formulation.
- Development of Policies e.g National Medicines Policies; In Ug - NPSSP III, IV.
- Improved data disclosure:
  - Surveys
  - Online drug registers by NDA
  - Consumer relations with NDA e.g SMS to inquire the registration of pharmacy, drug shop or manufacturer;
Cont’d Phase III 2016

- **Resource mobilization:**
  - Enabled raising funds to implement activities e.g.
  - QoM monitoring
  - Price & Availability of medicines monitoring
  - Development of NPSSP III
  - Development of NPSSP IV

- **Health system strengthening:**
  - HW training manual for PV
  - Mainstreaming PV reporting tool into HMIS
Cont’d

- **CSO capacity building**: Annual workshops built capacity of over 75 organisations on policy advocacy and budget analysis.

- **Community empowerment**:
  1. MeTA developed a peer-to-peer facilitators’ guide for adolescent health highlighting age-appropriate messages. This was approved by MoH in 2018 and tested in 3 districts (Mukono, Dokolo and Mayuge).
  2. Piloted social accountability on adolescent SRH which led to buy-in from district and sub-county level officials on improvements in adolescents SRH services.
Cont’d

- **Advocacy**
  - Increased public debate and reporting on medicine related issues e.g. Stop Stockouts campaign led to doubling of health budget in 2009
  - MeTA with partners have increased the awareness of Members of Parliament on access to sexual reproductive health and rights (SRHR) which has resulted in bold Parliamentary decisions on national SRHR policies and budgets
  - Working with partners through advocacy, more than two-fold increase in SRH commodities budget from UGX 8bn to 16bn in 2018.
  - As a result the preeclampsia campaign government has ring-fenced funding towards the procurement of magnesium sulphate.
  - At district level, Lira district leadership has constructed a preeclampsia ward at Lira Regional Referral Hospital and committed special budget to procure magnesium sulphate
Challenges and Opportunities

- **Challenges:**
  - Informal/coalition: Loose institutional arrangements
  - Insufficient funds and reliance on external projects:
    - To roll out desired projects.
    - To create visibility of good work.
  - Limited visibility

- **Opportunities**
  - MeTA is still the only widely inclusive multistakeholder forum on medicines.
  - Platform can be utilised for other sectors & multisectoral
  - Trusted research.
  - Commitment from policy makers and legislators.
ASANTE SANA
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Audience Q&A
July webinar

TBC  Regulating markups for pharmaceutical products: how much is enough?