Medicines Policy in Moldova

Workshop in Chisinau, Moldova

12 December 2016
Health Action International

• A non-for-profit global network

• Established in 1981

• Comprising public health NGOs, healthcare professionals, academics and consumers

• Based in Amsterdam & Brussels

• Working to increase access to essential medicines and improve their rational use through research and evidence-based advocacy

• HAI Europe funding sources: Executive Agency for Health and Consumers (EAHC); Open Society Foundations (OSF); Camino Foundation
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PART 1

Who has access to medicines?
Right to health in Moldova

Constitution of the Republic of Moldova

Article 36: Right to health protection
1. The right to health protection shall be guaranteed.
2. The minimum health insurance provided by the State shall be free.

Art 4: Human rights & freedoms
Standards in international law also apply and can be enforced in Moldova
Right to health in international law

• Right to health ≠ Right to be healthy
• Government has primary responsibility to protect and promote health
• Includes immediate provision of essential medicines as defined by WHO
• Non-discrimination and equality

Sources of international law:
Art 12. International Covenant of Economic, Social & Cultural Rights & General Comment No. 14
Making fair choices in providing access to healthcare

Recommendations from high-level group to WHO:

• Cover *everyone* with high-priority services.
• Eliminate out-of-pocket payments.
• Pay in advance for care.
Making fair choices in providing access to healthcare

Recommendations from high-level group to WHO:

- Fair payment is based on ability to pay, not on how much one needs the medicine.
Law on Compulsory Health Insurance no. 1585

1998 - essential package of emergency & primary care
- in-patient medicines & services provided without charge
- selected out-patient medicines are reimbursed

2009 - expanded coverage of low-income families

2010 - citizens of Moldova, regardless of their income level, are provided with equal opportunities for care
What are the vulnerable groups in Moldova?

Who misses out on health insurance?
Key points for universal access

- Essential medicines are part of everyone's right to health
- Law in Moldova covers most people with health insurance
- Medicines reimbursement for certain disease groups
- Certain vulnerable groups do not have access to medicines
PART 2

Which medicines are reimbursed?

Which medicines do patients have access to?
Which medicines are accessible?

The selection of medicines is limited to:

• Medicines that are developed
• Medicines that are marketed in Moldova
• (Often) Medicines that are reimbursed in Moldova
1. Drug development

Mismatch between public health needs & research priorities

- Resistance to antibiotics
- Diabet
- Alzheimer's and Dementia
- Cancer
- Tuberculosis
- Pandemic flu
- Depression
- COPD
- Alcohol
- Arthrose
- Heart disease
- HIV/AIDS
- Tropical diseases
- Malaria
- Postpartum hemorrhage
- Stroke
- Tobacco

http://www.spiegel.de/international/business/imi-research-diverges-from-who-priorities.html
1. Drug development

For-profit research & development selects the potential best sellers, not always the most needed drugs.

Examples:
- Child-sized medicines for tuberculosis & HIV
- Shorter treatments for tuberculosis
- Diagnostics for bacterial vs. viral infections in respiratory tract

2. Marketing Medicines

All medicines

Registered Medicines in Moldova

• Not every medicine on the market is important for patients
2. Medicines marketed in Moldova

Analysis of 1345 new market approvals for medicines in Europe (2000-2013)

Only 2% of new medicines licensed on the French market between 2000-2013 offered a real advance for some patients.

La revue Prescrire
2. Medicines marketed in Moldova

All medicines

Registered Medicines in Moldova

• Newer medicines are not always better.

• Some essential medicines are not marketed.
3. Selecting medicines to reimburse

All medicines

Registered medicines

National list of essential medicines

Essential medicines are those that satisfy the **priority health care needs** of the population.

WHO Model List of Essential Medicines

National list of essential medicines
http://amed.md/sites/default/files/Medicamente/Med-te%20esentiale%202011.pdf
3. Selecting medicines to reimburse

What are essential medicines?
Essential medicines are those that satisfy the priority health care needs of the population.

Selection criteria
Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

(Report to WHO Executive Board, January 2002)
3. Selecting medicines to reimburse

Purpose:
Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Benefits of essential medicines:
A limited range of carefully selected essential medicines leads to better health care, better drug management, and lower costs.

( WHO Expert Committee Report, April 2002 )
3. Selecting medicines to reimburse

Implementation
It is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

*If a medicine is considered essential, then it should become affordable for all.*

(WHO Expert Committee Report, April 2002)
Diabetes in Kyrgyzstan

Kyrgyzstan (2009)

Government Budget for Insulin

- $$$ Patented analogue insulins 13% of patients
- $ Generic insulin 26% of patients

3. Selecting medicines to reimburse

All medicines

Registered medicines

National list of essential medicines

Reimbursement list

List of medicines that the government subsidizes

Ideal situation

Reimbursement list
3. Selecting medicines to reimburse

All medicines

Registered medicines

National list of essential medicines

Reimbursement list
List of medicines that the government subsidizes

Actual situation
Deciding which medicines to reimburse:
Rank medicines in order of priority

Medicines with most health benefits at low cost
Medicines with fewer health benefits at higher cost
Rank medicines in order of priority

Ranking needs to:

- Consider the needs of the worst-off patients
- Involve patients & consumers in setting the criteria
- Be based on objective criteria and evidence
- Be used in a way that is consistent and transparent
Hepatitis C in Moldova

• Est. 120,000 people with chronic Hepatitis C in Moldova

• Essential medicines list or government subsidy: pegylated interferon and ribavirin
  • Many adverse effects
  • Offers treatment but not cure

• Sofosbuvir (Sovaldi) marketed in 2013
  • Significant health gains
  • Internationally: $$$$$
  • On WHO List of Essential Medicines (2015)

• Sofosbuvir in Moldova:
  X Essential medicines list (2011)
  X Reimbursed medicine (2016)
Key points when selecting medicines

• Use the essential medicines concept to select medicines

• An essential medicine should become available & affordable for everyone who needs it

• Select & reimburse medicines based on criteria and evidence

• Evidence-base should be publicly available

• Focus on best-buys
PART 3

What do medicines cost the patient?
Medicines prices: Not the same everywhere

Sofosbuvir for Hepatitis C

EUROPE: Price is €25,000 - €56,000 for 12 week course

INDIA: Price is $161 / bottle

Medicines prices: Not the same everywhere

Sofosbuvir for Hepatitis C

EUROPE: Price is €25,000 - €56,000 for 12 week course

*High price due to patent protection*

*Lower price thanks to ‘voluntary license’*

INDIA: Price is $161 / bottle

Medicines prices: Not linked to cost of production

Sofosbuvir for Hepatitis C

EUROPE: Price is €25,000 - €56,000 for 12 week course

INDIA: Price is $161 / bottle

Production costs $68 - $136 / treatment

Medicines prices: Not linked to cost of research & development

How much does it cost to research & develop a new medicines?

Pharmaceutical industry: $1 200 000 000

Non-profit drug developers: Drugs for Neglected Diseases initiative $150 000 000

What determines the costs for patients?
What determines the costs for patients?

Price of the medicine

Cost patients pay
65%

Government funding
35%
How to reduce costs for patients?

Price of the medicine

= 

Patient spending
How to reduce costs for patients?

Price of the medicine

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Patient spending
How to reduce costs for patients?

Price of the medicine

Patient receives medicine
How to reduce costs for patients?

1. Decrease medicines prices

Price of the medicine

Patient savings
How to reduce costs for patients?

Price of the medicine

1. Decrease medicines prices
How to reduce costs for patients?

1. Decrease medicines prices
2. Increase government funding

Price of the medicine

Patient savings
How to reduce costs for patients?

1. Decrease medicines prices

2. Increase government funding
How to reduce costs for patients?

1. Decrease medicines prices

2. Increase government funding
How to reduce costs for patients?

1. Decrease medicines prices
2. Increase government funding

Price of the medicine – Government funding = Cost for patients
Key questions

1. Is the **price of medicines too high**? Is the government doing enough to keep prices affordable?
Factors influencing the price of medicines

- Taxes
- Mark up & distribution costs
- National policies
- Policies to promote generics
- Price regulation policy
- Level of competition
- National patent law
- Procurement strategies
Ways to lower the price of medicines

• Compare prices with other countries or therapeutic groups (Reference Pricing)

• Promote the use of generics

• Many other options
Reference Pricing

• External – compare with prices in other countries

• Internal – compare with other treatments in therapeutic class
Reference Pricing

- **Goal**: An *objective measure to compare and set fair prices*
Reference Pricing

• **Goal:** An objective measure to compare and set fair prices

• Real challenges:
  • Actual prices are not known
Reference Pricing

• **Goal:** An objective measure to compare and set fair prices

• Real challenges:
  • Actual prices are not known
  • Methods for choosing comparators are not perfect
Reference Pricing

• **Goal:** An *objective measure to compare and set fair prices*

• Real challenges:
  • Actual prices are not known
  • Methods for choosing comparators are not perfect
  • Increase in generic price
National Medicines Policy

Medicines Selection
- Which medicines are essential?

Affordability & Financing
- How should medicines prices be set?
- How should generics be promoted?

Supply systems
- Will medicines be locally produced or imported?

Regulation
- How will the quality of medicines be tested?

Appropriate use
- Should medicines be advertised to doctors? To patients? To the public?

Research
- Which new medicines should be developed? How to decide?
Key questions

1. Is the **price of medicines too high**? Is the government doing enough to keep prices affordable?

2. Is the **government spending enough** to afford a basic package of essential medicines for everyone?
Affording basic essential medicines

Amount needed to buy basic package
(2016 Lancet Commission)

US$ 13-25/capita

Moldova government + patient spending (2010)

US$ 63/capita

High out-of-pocket & informal payments

How much funding is from the government?
Is money spent efficiently?
What about expensive medicines for non-communicable diseases?

- **Diabetes**: Insulin

- **Cardiovascular disease**: Lower cholesterol

- **Cancer**: Oncological drugs

  - Herceptin (breast cancer) €120,000 in UK
Key questions

1. Is the **price of medicines too high**? Is the government doing enough to keep prices affordable?

2. Is the **government spending enough** to afford a basic package of essential medicines for everyone?

3. Are the **costs for patients too high**? Are patients sufficiently protected from catastrophic spending?
Key points to bring down medicines costs

• National medicines policy can establish national priorities for:
  • Medicines pricing policies
  • Promotion of generics
  • Using TRIPs flexibilities

• **Sufficient and efficient government funding** through compulsory health insurance

• **Monitoring prices and affordability** to make sure patients are sufficiently protected from catastrophic spending
Thank you for your attention

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