Principles for the Rational Use of medicines

Nina Sautenkova, WHO, Regional Office for Europe
More than 4000 years of regulation in medicines area

Hammurabi code (~ 2000 b.c.):

• Doctor’s fee depends on financial possibilities of the patient:
  215. If patient is a wealthy man he pays 10 shekels
  216. If patient is a free man he pays 5 shekels
  217. If patient is a slave.... 2 Shekels

• Penalties:
  218. If a surgeon performs a major operation with a lancet and caused the death of a patient, they shall cut off his hands.
Medicines are old as world

• Medicines can prevent and treat diseases and can relieve pain and consequences of the disease...

• There is no ANY absolutely safe medicine. There is ALWAYS a certain degree of the risk.

• "To be treated you have to be a very healthy person, because apart from disease you have also to tolerate the medication”

Molier
History lessons

- Not all medicines safe for rats are safe for people
- **Thalidomide** was sold from 1957 to 1961 in 50 countries under 40 trade names
- **Thalidomide** was prescribed to pregnant women for morning sickness and light sleeping medicine
- 10,000 children were born with severe teratism

Minimum once a month WHO sends out warnings about withdrawals of medicines or other medical supplies from markets due to different causes
Plan of the presentation

1. Objectives of Health Systems in area of medicines and health technologies and Rational Use of medicines
2. Some characteristics of pharmaceutical sector
3. Public Health interests vs industry interests
4. Medicines use over time
5. ICIUM 2011, main concerns
6. Conclusions
Main objective of any Health system in area of medicines

• Provide all in need with efficacious, safe and quality medicines on affordable prices (both for individual patient and for health system)
• Objectives may and should differ depending on income level of the country and on cultural, ethical, economic preferences and traditions, etc.
Rational Use of medicines – Did our understanding change a lot during last 30 years? From Nairobi 1985 to Antalya 2011

• Rational use of drugs is an appropriate prescribing, marketing, and use, in accordance with national regulations and practices, of drugs approved by national authorities on the ground of safety, quality, and efficacy, the existence of an effective infrastructure and of sufficient affordable drugs of quality to meet needs being implied.

• Rational use of drugs demands that the appropriate drug is prescribed, that it is available at the right time at a price people can afford, that it is dispensed correctly, and that it is taken in the right dose at the right intervals and for the right length of time. The appropriate drug must be effective, and of acceptable quality and safety.


Rational Use of medicines - main principles

- RIGHT POLICY OBJECTIVES
- Objective and transparent SELECTION
- IMPLEMENTED TOOLS of RUM
- OBJECTIVE INFORMATION
- SYSTEM, SUPPORTING IMPLEMENTATION IN PLACE (practice, education, regulation of promotion, monitoring of use, etc)
Main stakeholders of pharmaceutical sector (Andreas Seiter, A practical approach to Pharmaceutical Policy, 2010)

- Multinational Research based companies
- Multinational generics companies
- Local manufacturers
- Brokers
- Procurement agents
- Importers and their agents
- Wholesalers
- Central medical stores
Main stakeholders (Andreas Seiter, A practical approach to Pharmaceutical Policy, 2010)

- Retail pharmacies and Drug sellers
- Prescribers
- Consumers
- Policy makers
- Regulatory and Executive Agencies
- Expert commissions and advisers
Main stakeholders (Andreas Seiter, A practical approach to Pharmaceutical Policy, 2010)

- Civil society (NGOs)
- Patient’s organizations
- International Agencies and donors
- Public purchasers
- Payers (public)
- Pharmaceutical benefit managers (private HI)
- Consultants
Regulation of Pharmaceutical Sector (efficacy, safety, quality, Rational use)

• Pharmaceutical sector is one of the most regulated in the world

Consumer can not assess Quality, Efficacy and Safety. The only thing he can see is the price...
Even specialists have difficulties if they are not trained specifically;

PHARMACEUTICAL MARKET IS AN EXPERT DRIVEN MARKET
INNOVATION: Creation of new medicines

Pre-clinical studies: 2-3 years
Clinical development: 5-7 years
Use: 1-2 years

Total estimated time: 8-12 years

Level of success: >10,000 molecules

Investments (mln. €): Up to 1.5 billion

~10 potential medicines

1 new medicines

Piperska training course, March 19-21, 2012

* Include costs of all non successful products
Global Pharmaceutical Market

From: CMR International & IMS Health, 2008

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### Unethical promotion: penalties and profits

<table>
<thead>
<tr>
<th>company</th>
<th>medicine</th>
<th>Penalty (year)</th>
<th>Profit (years)</th>
</tr>
</thead>
</table>

HAI, 2010
Ratings of 961 new drugs and indications in France, 1999 to 2008 – *La Revue Prescrire*

Understanding and Responding to Pharmaceutical Promotion, WHO/HAI,
ICIUM 2011

• Irrational medicines use is a worldwide problem that is receiving insufficient attention
  – Little routine monitoring, few large scale interventions and poor policy framework to improve use (ICIUM 2004)
  – 1033 surveys conducted in 104 countries in period 1999-2009

K. Holloway et al, ICIUM 2011
Medicines use over time

- % Px with ABs (n=50,73,78,74,101,43,15)
- % Px with INJs (n=34,60,68,57,65,29,17)
- % EML drugs (n=8,30,45,51,39,13,12)
- % Generic drugs (n=13,49,47,53,31,20,14)
- % STG compliance (n=15,62,55,39,54,20,10)
- Av.no.drugs/Px (n=46,92,94,90,79,32,19)
Guideline adherence over time by region

% patients treated in compliance with guidelines

Africa (n=12,59,54,28)
L.America (n=2,15,11,1)
Europe/Mediterr (n=2,12,15,2)
Asia/Pacific (n=2,37,23,4)

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## Intervention impact: largest % change in any medicines use outcome measured in each study

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>No. studies</th>
<th>Median impact</th>
<th>25,75\text{th} centiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed materials</td>
<td>6</td>
<td>8%</td>
<td>4%, 10%</td>
</tr>
<tr>
<td>National policy</td>
<td>6</td>
<td>17%</td>
<td>4%, 23%</td>
</tr>
<tr>
<td>Economic strategies</td>
<td>8</td>
<td>13%</td>
<td>8%, 19%</td>
</tr>
<tr>
<td>Provider education</td>
<td>29</td>
<td>17%</td>
<td>9%, 22%</td>
</tr>
<tr>
<td>Consumer education</td>
<td>3</td>
<td>26%</td>
<td>13%, 27%</td>
</tr>
<tr>
<td>Provider+consumer ed</td>
<td>16</td>
<td>21%</td>
<td>11%, 24%</td>
</tr>
<tr>
<td>Provider supervision</td>
<td>26</td>
<td>18%</td>
<td>14%, 31%</td>
</tr>
<tr>
<td>Provider group process</td>
<td>9</td>
<td>36%</td>
<td>19%, 59%</td>
</tr>
<tr>
<td>Essential drug program</td>
<td>4</td>
<td>27%</td>
<td>22%, 40%</td>
</tr>
<tr>
<td>Community case mgt</td>
<td>10</td>
<td>33%</td>
<td>28%, 39%</td>
</tr>
<tr>
<td><strong>Provider+consumer educ &amp; supervision</strong></td>
<td><strong>7</strong></td>
<td><strong>40%</strong></td>
<td><strong>18%, 54%</strong></td>
</tr>
</tbody>
</table>
• Key Lessons Learnt

– Medicines use remains poor in all regions over the past 25 years and is worse in the private compared to the public sector

– Effective interventions are those with multiple components e.g. education for providers and consumers with provider supervision or group process

– Medicines use database should be used to monitor drug use and intervention impact
ICIUM 2011

http://www.inrud.org/ICIUM/ICIUM-2011.cfm

• Concerns re methodology and indicators used for studies of rational use
• Concerns regarding massive genericization without simultaneous strengthening of regulatory requirements for efficacy, quality and safety of medicines
• Concerns regarding poor regulation of promotion (in EURO region especially relevant, as national pharmaceutical policies should be balanced between support of manufacturers and effectiveness of health systems)
General conclusions

• Each country has to rethink incentives for all stakeholders to play by the rules (incentives and penalties)

• Revision and update of treatment guidelines participatory EBM process, driven by Regulators

• Objective Information for users (prescribers and patients) and medicines use databases maintained in all countries

• Only complex measures really matter
Thank you for your attention!!!!

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