OTC Medicines
The role of good classification practices in promoting medication safety and accessibility in Europe

Patients’ awareness and education with respect to the safe and appropriate use of medicines, with special attention to OTC medicines
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Global Federation of SMI associations

- Not-for-profit Non Governmental Organization

“WSMI’s mission is to create and maintain an international environment intended to improve the opportunities for people to manage their own health through the responsible use of safe and effective nonprescription medicines.”

Focus on three areas

- Supporting OTC market development (esp. in emerging and developing markets)
- Helping to develop the evidence base of information and support for the OTC sector
- Linking with multilateral and intergovernmental organisations (e.g. WHO, WTO, WMA, FIP, others)
Outline

• Public health and economic value of self-care and self-medication
• New system supporting safe and appropriate self-care
• Benefit – Risk approach for proportional regulation
Self-care and self-medication

“Self-Care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider.”

WHO working group, 2013

“Self-medication empowers patients to treat or prevent short term or chronic illnesses which they consider not requiring the consultation of a physician or which may be treated by the people after an initial medical diagnosis.”

European Commission, 2008

“Self-care includes the actions people take for themselves (...) to stay fit and maintain good physical and mental health (...) prevent illness or accidents; care for minor ailments and long-term conditions.”

UK Department of Health, Self-Care – A real choice, 2004
Challenges for Health Systems

Demographic changes (ageing)

NCDs, life-style diseases ("diseases of the affluent")

Financial realities, challenges

Globalization, societal change (health awareness, demand for involvement)
### 10 minor ailment responsible for over 75% of consultations

<table>
<thead>
<tr>
<th>MA</th>
<th>Total consultations (millions)</th>
</tr>
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<tbody>
<tr>
<td>Back Pain</td>
<td>8.4</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>6.8</td>
</tr>
<tr>
<td>Heartburn and indigestion</td>
<td>6.8</td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>5.3</td>
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<tr>
<td>Constipation</td>
<td>4.3</td>
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<tr>
<td>Migraine</td>
<td>2.7</td>
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<tr>
<td>Cough</td>
<td>2.6</td>
</tr>
<tr>
<td>Acne</td>
<td>2.4</td>
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<tr>
<td>Sprains and Strains</td>
<td>2.2</td>
</tr>
<tr>
<td>Headache</td>
<td>1.8</td>
</tr>
<tr>
<td>Earache</td>
<td>1.7</td>
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<tr>
<td>Psoriasis</td>
<td>1.7</td>
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<tr>
<td>Conjunctivitis</td>
<td>1.3</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>1.2</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>1.2</td>
</tr>
<tr>
<td>Haemorrhoids</td>
<td>0.9</td>
</tr>
<tr>
<td>Cystitis</td>
<td>0.7</td>
</tr>
<tr>
<td>Hay Fever</td>
<td>0.7</td>
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### Burden on HC systems & potential for cost savings

<table>
<thead>
<tr>
<th></th>
<th>USA (Booz &amp; Co study, CHPA, 2012)</th>
<th>Australia (MUCHE OTC Value Study 2014)</th>
<th>EU (AESGP, Economic and public health value, 2004)</th>
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<tbody>
<tr>
<td>Avoided doctors visits</td>
<td>77 billion USD</td>
<td>3.86 billion AUD</td>
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<tr>
<td>Drug costs</td>
<td>25 billion USD</td>
<td></td>
<td></td>
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<tr>
<td>Productivity</td>
<td>6.55 billion AUD</td>
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</tbody>
</table>
| Total               | 102 billion USD                   | "For every USD spent on OTC medicines, the U.S. healthcare system saves USD 6-7 in avoided costs."
| Productivity        | 23 billion USD                    | Estimated savings in productivity loss |
| Health Care system  | 4 billion USD                     | Estimated additional annual costs in emergency department visits |
|                     | Over 16 billion EUR               | Annual savings by shifting 5% of care to self-medication |
Extending the scope of self-medication

- Prevention and management of long-term conditions and life-style aspects
- Managing health vs. treating (minor) illness
- Reflecting on innovation, value creation, consumer/patient centered approaches and social media

Disease / Indication Map
AESGP study for DG Sanco

Doctor consultation & other health professional advice & patient self-management (with/without medical advice)
Patient Engagement

- **Health literacy** - cognitive and social skills determining motivation and ability to access, understand and use information to promote and maintain health

  WHO definition of Health Literacy

- **Patient activation** – knowledge, skills, ability and willingness to manage own health and care

- **Patient engagement** – combines patient activation with an intervention
  - More activated and engaged patients have better health outcomes
  - Patients with lowest activation score incurred up to 21% higher costs than patients with highest activation score

Health Policy Briefs, Health Affairs, February 2013
“People want to have a more active role in their own healthcare, including in the decisions about what medicines to take. When it comes to access to self-medication, good information and support translate into empowered patients who can benefit fully from the opportunities of self-care and who can practise it safely and effectively with informed choice.”

Report of the working group on promoting good governance of non-prescription, Drugs in Europe, June 2013
Evolving landscape for self-care

- Demand for involvement
- Patients / consumer organizations
- Internet (NetDoctor, social media etc.)

- mHealth
- Health literacy
- Patient empowerment

**Self Care**

- Daily choices
- Lifestyle
- Self-managed ailments

**Collaborative Care**

- Minor ailments
- Chronic conditions
- Acute conditions

**Medical Care**

- Compulsory psychiatric Care
- Major trauma

- Limited engagement in healthcare
- Limited in influencing own health
- Engages in improvement of own health
- Able to influence own health

Classic medical care system

Empowered and health-literate people-driven self-care system
Understanding Influences on Self-Care Behaviour

Advertising
- Broadcast
- Print
- Web
- Social

Awareness

Need recognition

Desire to Act
- Prevention
- Treatment

Information Sources
- Doctor
- Pharmacist
- Friends/Family
- Web

Information search

Evaluation of alternatives

Purchase Decision
- Point of sale
  - Labels
  - In store placement
  - Information

Use of product
- Label adherence
- Satisfaction
- Adoption
- Intent to repurchase

Post-purchase behaviour

The Consumer Journey, WSMI, 2014
Self-care and OTC medication
The roles for consumers, pharmacists & HCPs

**Current picture**
Pharmacist: building relationship, but limited in proactive involvement

Consumer: self-selecting with limited advice and judging themselves when necessary to visit GP/Nurse

GPs/Nurses: Willing to Rx for minor ailments and not directing patients to pharmacist due to lack of trust

**Future picture**
Pharmacy staff proactively involved in patient self-care

Confident consumer selects OTC medicine and makes pharmacist first contact if symptoms persist

GP/Nurse feels confident to suggest self-care route and trusts pharmacist capability

Based on PAGB, 2012
New paradigm

• Self-care is the foundation of health care
• Economic studies demonstrating the potential for huge cost savings to the HC system
• ... but ... in evaluating classification, cost and public benefit of OTC medication are not (always) taken into account
Regulation for classification

Appropriate regulation is based on transparency, accountability, proportionality, efficacy and simplification assessing benefits and risks

**BENEFIT DOMAINS**
- Convenience/improved access
- Improved outcomes
  - Symptom relieve/quality of life
  - Significant impact on morbidity/mortality
- Public health benefits
- Increased consumer involvement in health
- Economics
  - Utilization of other health care resources
  - Consumer time

**RISK DOMAINS**
- AE when used as directed – limited relevance
- AE with
  - unintended misuse
  - intentional misuse with therapeutic intent
  - accidental ingestion
  - intentional overdose (“Recreational” intent, suicidal intent)
- Worsened outcome from delay in optimal treatment
Improving the benefit-risk (B/R) assessment process for non-prescription medicines

Example of value tree use: nonprescription nicotine replacement therapies (NRTs)

Common Domains for Nonprescription Drugs
- Improved access
- Improved clinical outcomes
- Improved public health
- Enhanced consumer involvement
- Economic benefits

NRT-Specific Characteristics
- Increased cessation attempts
- Increased number of consumer successfully stopping smoking
- Decreased smoking rates
- Increased adoption of healthy lifestyles
- Increased adverse events due to exceeding dose/duration
- Combined use with smoking
- Use during pregnancy
- Abuse, abuse by adolescents
- Decreased success rates vs. healthcare provider supervised

Benefit Considerations
- Improved access
- Improved clinical outcomes
- Improved public health
- Enhanced consumer involvement
- Economic benefits

Risk Considerations
- Unintended misuse
- Intentional misuse with therapeutic intent
- Accidental ingestion
- Intentional overdose
- Worsened outcome due to self-management

Improving the benefit-risk (B/R) assessment process for non-prescription medicines

- Integrate value tree to decision making framework, emphasizing transparency, communication and evidence-based decision making

- Referenced in national guidelines (e.g. UK, Canada, New Zealand)

- Propose to refer to in EDQM Expert Committee documents

Adapted from International Risk Governance Council (IRGC) Framework: maximize communication and transparency
Purpose of Benefit-Risk approach

- Allow comprehensive identification of relevant benefit and risk attributes for specific nonprescription drug candidates
- Facilitates early agreement between sponsors and regulators on most important characteristics, important data gaps and approach to integrated benefit-risk assessment
- Flexibly supports varied benefit-risk methods, particularly multiple criteria analysis
- Integrated into Framework that emphasizes transparency, communication and evidence-based decision making supplemented by balanced expert opinion
Summary

• OTC sector is different from the Rx sector
  • Public Health and economic benefit
• Empowerment and active participation of all stakeholders is key
  • consumers, pharmacists, HCPs, others
• Need for an appropriate regulation based on proportionality and transparency
  • benefit-risk approach
Thank you

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