Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

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Towards EU Accession: Serbia's Regulatory Challenges, Expectations And Opportunities

Acquis Communautaire – Perspectives For Industry

29-30 November 2010

Belgrade

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Non-prescription medicines

- 50% of all medicines sold have the status of non-prescription
- Primarily consisting of established substances
- Innovation e.g. through move of substances from prescription to non-prescription status ("switching")

Pharmaceutical EU legislation

- Started in 1965
- Several major revisions
- Complex mix between EU and national rules

Level of harmonisation

- High: marketing authorisation, labels, leaflets
- Medium: advertising, classification
- Low: pricing, reimbursement, distribution

Market access

- Basic criteria for proof of efficacy, safety and quality are harmonised
- Centralised procedure possible for innovative non-prescription medicines: classification status harmonised
- Mutual recognition / decentralised procedure: classification status national
- National authorisations for well-established substances still possible

Classification of medicines

- *Medicinal products shall be subject to medical prescription where they:*
  - are likely to present a danger, even when used correctly or,
  - are frequently and to a very wide extent used incorrectly or,
  - contain substances which require further investigation or,
  - are to be administered parenterally.

- *Remainder are non-prescription medicines*

Guideline on changing the classification for the supply of a medicinal products for human use

Revised version of 26 January 2006:

http://pharmacos.eudra.org/F2/eudralex/vol-2/C/switchguide_160106.pdf

- Detailed explanation of the basic criteria
- Clarification of data requirements
- Clarification of exclusivity provisions

AESGP "Switch Database"

Available via:

http://www.aesgp.be/publications/otcIngredientTables.asp

Shows numerous important switches to non-prescription status over the last years

Package leaflets

- "The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals…"

- "The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use"

- European Commission to submit report on current shortcomings and possible improvements by 2013

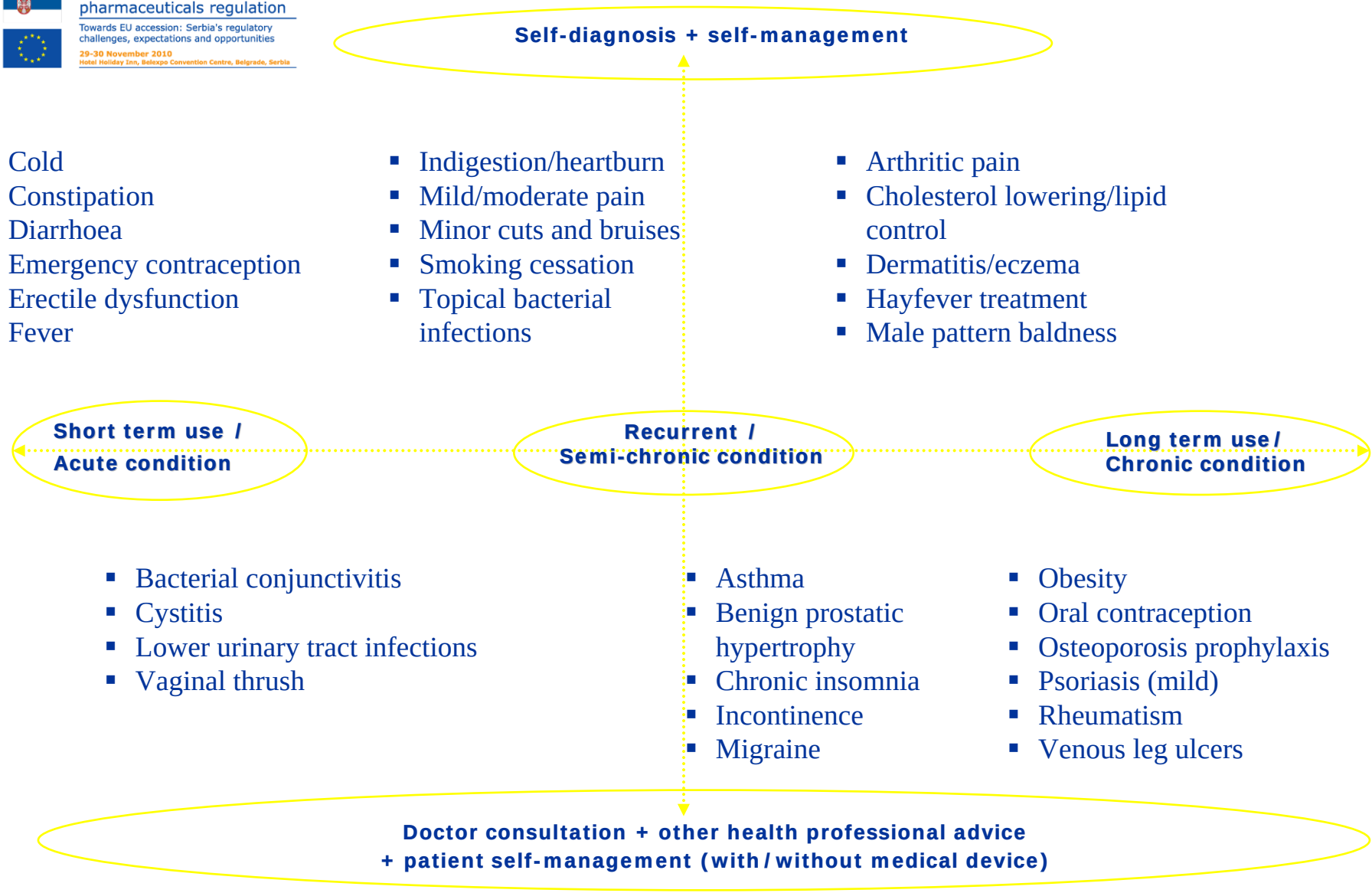
Advertising

- In principle all non-prescription medicines may be advertised in all media
- Different control mechanisms
- Trend towards abandoning state pre-control

Future pharma policy

"... non-prescription medicines ... play an important role since they offer economic as well as social benefits. 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. Consequently, access and availability of these medical products require particular attention."

Source: Communication of the European Commission on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector" of 10 December 2008



Source: AESGP study on new indications for self-medication and related information needs carried out for DG SANCO of the European Commission


AESGP
ASSOCIATION OF THE EUROPEAN SELF-MEDICATION INDUSTRY
Smart Regulation 2015
THE FUTURE REGULATION OF SELF-CARE

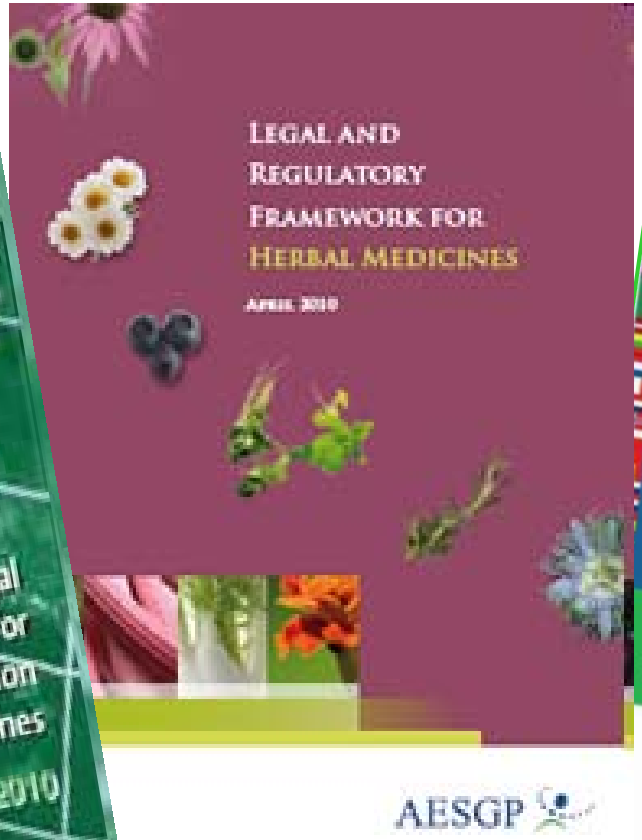
Close collaboration with stakeholders

- Health professions
  - Medical doctors
  - Pharmacists
- Patients'/consumers' organisations
- Governmental organisations

"Borderline areas"

- Food / food supplements
- Medical devices
- Cosmetics


AESGP
Economic and Legal Framework for Non-Prescription Medicines
JUNE 2010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Self-care:

The first choice

in health care