F3: MARKET ACCESS IN CENTRAL AND EASTERN EUROPE: WHAT ARE THE DRIVERS AND CHALLENGES?

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Speakers

• **MODERATOR: Olha Zaliska**, PhD, DSci, Professor, Head of Department of Management and Economy of Pharmacy, Medicine Technology and Pharmacoeconomics, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine
• **SPEAKERS:**
  • **Joanna Lis**, PhD, Assistant Professor, Department of Pharmacoeconomics, Medical University of Warsaw, Market Access Director, Sanofi Warsaw, Poland
  • **Oresta Pinlazhko**, PhD, President, ISPOR Ukraine Chapter, Senior Lecturer, Department of Management and Economy of Pharmacy, Medicine Technology and Pharmacoeconomics, Postgraduate Faculty, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine, Member of Expert Committee of Ministry of Health of Ukraine
  • **Vlad Zah**, PhD, Health Economist, CEO, ZRx Outcomes Research Inc., Serbia
  • **Bertalan Németh**, MSc, President, ISPOR Hungary Chapter, Senior Health Economist, Syreon Research Institute, Budapest, Hungary
HTA in Serbia: Drivers and Challenges
Burden of Disease

- 36.4% of the adults - daily smokers
- Alcohol abuse 13.3% of the population (22.1% of men and 4.6% of women)
- Half of population pre obese & obese
- 47.5% of the population had hypertension or potential hypertension
- Only 8.8% of the population deal with recreation at least three times a week

Source: National Health Survey, 2013 - Institute of Public Health of Serbia

HTA in Serbia: Drivers and Challenges – National health account data by ICD 10

X-axis ICD-10 codes:

- Certain infectious and parasitic diseases (A00-B99)
- Diseases of the circulatory system (I00-I99)
- Diseases of the digestive system (K00-K93)
- Diseases of the genitourinary system (N00-N99)

Source: National Health Account - Institute of Public Health of Serbia
Market Access in Serbia: Drivers and Challenges

The criteria for placing the drug on the Drug List

• General criteria:
  – pharmacotherapeutic justification
  – pharmacoeconomic justification
  – funding provided by the Financial Plan of the Republic Fund

• Specific criteria:
  – managed entry agreements
  – priority order

Source: Rulebook on Criteria for Listing of Reimbursement Medicines

HTA in Serbia: Medicine Reimbursement Flow

Medicine Licensee

ALIMS - Drug Registration

MoH & MoC Max price

Negotiation Commission

NIF - Dossier verified

NIF PE Commission

REC (Rep. Exp. Com.) Medicine Prioritization

Reimbursement List of Medicines

NIF Management Board Ministry of Health Government

CKM (Central Commission Medicines) Priority List
HTA in Serbia: Medicine Reimbursement Flow – alternative solution with new draft law implementation

- ALIMS - Drug Registration
- MoH & MoC Max price
  - 30 days
- NIF - Dossier verified + Appraisal
- Negotiation Commission
- REC (Rep. Exp. Com.) Medicine Prioritization + PT Value
- CKM (Central Commission Medicines) Priority List
- HTA Agency – PE + PT Value
- Medicine Licensee
- 120 days

- Reimbursement List of Medicines
- NIF Management Board
- Ministry of Health Government
- 60 days

- 300 days

HTA in Serbia: Drivers and Challenges

Requirements

- Criteria for transparent decision making
- DRG implementation with realistic values
- Real World Data analytics
- Rare Diseases compartmentalization into a separate budget without option to go to Drug List (like other medicines) – currently exists